

H.R. 2480, INSPECTOR GENERAL FOR MEDICARE AND MEDICAID ACT OF 1995; H.R. 3224, THE HEALTH CARE FRAUD AND ABUSE PREVENTION ACT OF 1996; AND H.R. 1850, HEALTH FRAUD AND ABUSE ACT OF 1995

JOINT HEARING
BEFORE THE
SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS
AND THE
SUBCOMMITTEE ON GOVERNMENT MANAGEMENT,
INFORMATION, AND TECHNOLOGY
OF THE
COMMITTEE ON GOVERNMENT
REFORM AND OVERSIGHT
HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

ON

H.R. 2480

TO ESTABLISH AN OFFICE OF INSPECTOR GENERAL FOR THE
MEDICARE AND MEDICAID PROGRAMS

ON

H.R. 3224

TO IMPROVE FEDERAL EFFORTS TO COMBAT FRAUD AND ABUSE
AGAINST HEALTH CARE PROGRAMS, AND FOR OTHER PURPOSES

AND

H.R. 1850

TO IMPROVE FEDERAL ENFORCEMENT AGAINST HEALTH CARE FRAUD
AND ABUSE

MAY 2, 1996

Printed for the use of the Committee on Government Reform and Oversight



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H.R. 2480, INSPECTOR GENERAL FOR MEDICARE AND MEDICAID ACT OF 1995; H.R. 3224, THE HEALTH CARE FRAUD AND ABUSE PREVENTION ACT OF 1996; AND H.R. 1850, HEALTH FRAUD AND ABUSE ACT OF 1995

THURSDAY, MAY 2, 1996

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS, JOINT WITH THE SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY, COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,

Washington, DC.

The subcommittees met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Stephen Horn and Hon. Christopher Shays (chairmen of the subcommittees) presiding.

Present: Representatives Horn, Shays, Schiff, Davis, and Towns.

Ex officio present: Representative Clinger.

Also present: Representative Hastert.

Staff present: J. Russell George, staff director and counsel; Mark Uncapher, professional staff member and counsel; and Andrew G. Richardson, clerk, Subcommittee on Government Management, Information, and Technology; Lawrence J. Halloran, staff director and counsel; Kate Hickey, and Robert Newman, professional staff members; and Thomas M. Costa, clerk, Subcommittee on Human Resources and Intergovernmental Relations; and David McMillen, Cheryl Phelps, and Mark Stephenson, minority professional staff members.

Mr. HORN. A quorum being present, this joint session of the Subcommittee on Government Management, Information, and Technology and the Subcommittee on Human Resources and Intergovernmental Relations will come to order.

This morning's hearing will consider several legislative proposals designed to combat waste, fraud, and abuse in the Medicare and Medicaid programs. In November 1995, our subcommittees held a joint hearing that considered, among other matters, how existing information technology processes could be incorporated into the Medicare claims system to more effectively identify fraud.

As part of our subcommittee's oversight responsibilities under the Inspectors General Act, the Government Management Subcommittee has also previously received testimony from the Inspec-

tor General for the Department of the Health and Human Services concerning health care fraud.

The General Accounting Office has estimated that, as a result of fraud and waste, the losses to the Federal Government amount to approximately 10 percent of the over \$34 billion spent each year on Medicare and Medicaid programs. These losses, over \$34 billion each year, are a truly staggering sum. Despite the efforts of many agencies whose goal is uncovering these abuses, we all know that far too much remains undetected.

In that regard, this hearing will consider three legislative proposals: H.R. 3224, the Health Care Fraud and Abuse Prevention Act of 1996, was introduced on March 29 by Representative Steven Schiff and Human Resources Subcommittee Chairman Chris Shays, who will preside over much of this morning's hearing. Their bill modifies legislation that they previously introduced which would have expanded law enforcement tools for combating health care fraud.

H.R. 1850, the Health Care Fraud and Abuse Act, was introduced last summer by the ranking member of the Human Resources Subcommittee, Representative Ed Towns of New York. It is intended to improve coordination among agencies with fraud detection responsibility. H.R. 2480 was introduced by Representative Jack Quinn, who is on his way here, and that was introduced last October. It would establish a new Inspector General for Medicare and Medicaid programs.

Each of these bills seeks to enhance the effectiveness of the management of the Medicare and Medicaid programs. They would provide new deterrence weapons to the Department of Health and Human Services and the Department of Justice in their fight against fraud. With a problem this serious, we are very receptive to good ideas.

Our witnesses include Representative Quinn of New York; Michael Mangano, the Deputy Inspector General of the Department of Health and Human Services; Darrell Foreman, the representative of the Home Health Care Market Group of the Health Industry Distributors Association; and Rick Doherty, a spokesman for the National Association for Medical Equipment Services.

We thank each of you for joining us and we look forward to your testimony later today.

It is my pleasure now to yield to my co-chair of this hearing, the distinguished Member from Connecticut, Representative Christopher Shays.

Mr. Shays.

[The prepared statement of Hon. Stephen Horn and the texts of H.R. 2480, H.R. 3224, and H.R. 1850, follow:]

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OPENING STATEMENT BY THE HONORABLE STEPHEN HORN, CHAIRMAN SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION AND TECHNOLOGY MAY 2, 1996

THIS MORNING'S HEARING WILL CONSIDER SEVERAL LEGISLATIVE PROPOSALS
DESIGNED TO COMBAT WASTE, FRAUD AND ABUSE IN THE MEDICARE AND MEDICAID
PROGRAMS.

IN NOVEMBER 1995 OUR SUBCOMMITTEES HELD A JOINT HEARING THAT
CONSIDERED, AMONG OTHER MATTERS, HOW EXISTING INFORMATION TECHNOLOGY
PROCESSES COULD BE INCORPORATED INTO THE MEDICARE CLAIMS SYSTEM TO MORE
EFFECTIVELY IDENTIFY FRAUD. THE GOVERNMENT MANAGEMENT SUBCOMMITTEE HAS
ALSO PREVIOUSLY RECEIVED TESTIMONY FROM THE INSPECTOR GENERAL FOR THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES CONCERNING HEALTH CARE FRAUD, AS
PART OF OUR SUBCOMMITTEE'S OVERSIGHT RESPONSIBILITIES FOR THE INSPECTOR
GENERAL ACT.

THE GENERAL ACCOUNTING OFFICE HAS ESTIMATED THAT LOSSES TO THE FEDERAL
GOVERNMENT, AS A RESULT OF FRAUD AND WASTE, AMOUNT TO APPROXIMATELY 10
PERCENT OF THE OVER \$340 BILLION SPENT EACH YEAR ON THE MEDICARE AND MEDICAID
PROGRAMS. THOSE LOSSES, OVER \$34 BILLION EACH YEAR, ARE A TRULY STAGGERING
SUM. DESPITE THE EFFORTS OF MANY AGENCIES TASKED WITH UNCOVERING THESE
ABUSES, WE ALL KNOW THAT FAR TOO MUCH REMAINS UNDETECTED.

IN THAT REGARD THIS HEARING WILL CONSIDER THREE LEGISLATIVE PROPOSALS:

- ♦ H.R. 3224, "THE HEALTH CARE FRAUD AND ABUSE PREVENTION ACT OF 1996," INTRODUCED ON MARCH 29TH BY REPRESENTATIVE STEVEN SCHIFF AND HUMAN RESOURCES SUBCOMMITTEE CHAIRMAN CHRIS SHAYS. THEIR BILL MODIFIES LEGISLATION THAT THEY PREVIOUSLY INTRODUCED WHICH WOULD HAVE EXPANDED LAW ENFORCEMENT TOOLS FOR COMBATING HEALTH CARE FRAUD.
- ♦ H.R. 1850, "THE HEALTH CARE FRAUD AND ABUSE ACT," WAS INTRODUCED LAST SUMMER BY THE RANKING MEMBER OF THE HUMAN RESOURCES SUBCOMMITTEE, REP. ED TOWNS. IT IS INTENDED TO IMPROVE CO-ORDINATION AMONG AGENCIES WITH FRAUD DETECTION RESPONSIBILITY.
- ♦ H.R. 2480 WAS BEEN INTRODUCED BY REP. JACK QUINN LAST OCTOBER, AND WOULD ESTABLISH A NEW INSPECTOR GENERAL FOR THE MEDICARE AND MEDICAID PROGRAMS.

EACH OF THESE BILLS SEEKS TO ENHANCE THE EFFECTIVENESS OF THE MANAGEMENT OF THE MEDICARE AND MEDICAID PROGRAMS. THEY OFFER NEW DETERRENCE WEAPONS TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF JUSTICE IN THEIR FIGHT AGAINST FRAUD. WITH A PROBLEM THIS SERIOUS, WE ARE RECEPTIVE TO GOOD IDEAS.

OUR WITNESSES INCLUDE REP. QUINN OF NEW YORK; THE DEPUTY INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, MICHAEL MANGANO; A REPRESENTATIVE OF THE HOME HEALTH CARE MARKET GROUP OF THE HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION, DARRELL FOREMAN AND A SPOKESMAN FOR THE NATIONAL ASSOCIATION FOR MEDICAL EQUIPMENT SERVICES, RICK DOHERTY.

WE THANK YOU ALL FOR JOINING US, AND WE LOOK FORWARD TO YOUR TESTIMONY.

104TH CONGRESS
1ST SESSION

H. R. 2480

To establish an Office of Inspector General for the Medicare and Medicaid Programs.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 13, 1995

Mr. QUINN introduced the following bill; which was referred to the Committee on Government Reform and Oversight, and in addition to the Committees on Ways and Means and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish an Office of Inspector General for the Medicare and Medicaid Programs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Inspector General for
5 Medicare and Medicaid Act of 1995".

1 **SEC. 2. ESTABLISHMENT OF OFFICE OF INSPECTOR GEN-**
2 **ERAL FOR THE MEDICARE AND MEDICAID**
3 **PROGRAMS.**

4 (a) **ESTABLISHMENT AS INDEPENDENT AGENCY.—**

5 There is established as an independent agency in the exec-
6 utive branch of the Government an agency which shall be
7 known as the “Office of the Inspector General for the
8 Medicare and Medicaid Programs”.

9 (b) **PURPOSE.—**The purpose of the Office shall be to
10 supervise, oversee, and audit the medicare and medicaid
11 programs as provided for under titles XVIII and XIX of
12 the Social Security Act (42 U.S.C. 1395 et seq.).

13 (c) **INSPECTOR GENERAL.—**

14 (1) **IN GENERAL.—**The Office shall be under
15 the direction and control of the Inspector General
16 for the Medicare and Medicaid Programs.

17 (2) **APPOINTMENT.—**The Inspector General
18 shall be appointed in accordance with section 3 of
19 the Inspector General Act of 1978 (5 U.S.C. App.).

20 (3) **DUTIES.—**The Inspector General shall per-
21 form his duties in accordance with the provisions of
22 section 8G of the Inspector General Act of 1978 (5
23 U.S.C. App.).

1 **SEC. 3. SPECIAL PROVISIONS RELATING TO INSPECTOR**
2 **GENERAL FOR THE MEDICARE AND MEDIC-**
3 **AID PROGRAMS.**

4 (a) SPECIAL PROVISIONS.—The Inspector General
5 Act of 1978 (5 U.S.C. App.) is amended—

6 (1) by redesignating the last two sections (each
7 designated as section 8G) appearing before section 9
8 as sections 8II and 8I, respectively;

9 (2) in section 8I (as so redesignated)—

10 (A) by striking “8D, or 8E” and inserting
11 “8D, 8E, or 8G”; and

12 (B) by striking “8F(a)” and inserting
13 “8II(a)”; and

14 (3) by inserting after section 8F the following:

15 “SPECIAL PROVISIONS RELATING TO INSPECTOR
16 GENERAL FOR THE MEDICARE AND MEDICAID PROGRAMS

17 “SEC. 8G. DUTIES.—In addition to other duties and
18 responsibilities specified in this Act, the Inspector General
19 for the Medicare and Medicaid Programs shall—

20 “(1) supervise, direct, and control all functions
21 and duties of the Office of the Inspector General for
22 the Medicare and Medicaid Programs;

23 “(2) prevent and detect waste, fraud, and abuse
24 in the medicare and medicaid programs as provided
25 for under titles XVIII and XIX of the Social Secu-
26 rity Act (42 U.S.C. 1395 et seq.); and

1 “(3) coordinate all audits, investigations, in-
2 spections, and other activities for the purpose of pro-
3 moting economy and efficiency in the administration
4 of the medicare and medicaid programs.”.

5 (b) DESIGNATION OF OFFICE OF INSPECTOR GEN-
6 ERAL FOR THE MEDICARE AND MEDICAID PROGRAMS.—
7 Section 11 of the Inspector General Act of 1978 is amend-
8 ed in paragraph (2) by inserting “, or Office of Inspector
9 General for the Medicare and Medicaid Programs” before
10 “; as the case may be;”.

11 **SEC. 4. COMPENSATION**

12 Section 5315 of title 5, United States Code, is
13 amended by adding at the end the following:

14 “Inspector General for the Medicare and Medicaid
15 Programs.”.

16 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

17 There are hereby authorized to be appropriated such
18 sums as may be necessary to carry out the purposes of
19 this Act.

○

104TH CONGRESS
2D SESSION

H. R. 3224

To improve Federal efforts to combat fraud and abuse against health care programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 1996

Mr. SCHIFF (for himself and Mr. SHAYS) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committees on Government Reform and Oversight, Ways and Means, and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To improve Federal efforts to combat fraud and abuse against health care programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Health Care Fraud and Abuse Prevention Act of 1996”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—COORDINATION OF FEDERAL ENFORCEMENT

2

- Sec. 101. Federal enforcement by Inspectors General and Attorney General.
- Sec. 102. State enforcement.
- Sec. 103. Payments to States.
- Sec. 104. Health Care Fraud and Abuse Control Account.
- Sec. 105. Acceptance of gifts, bequests, and devises.
- Sec. 106. Reimbursements of expenses and other payments to participating agencies.
- Sec. 107. Account Payments Advisory Board.
- Sec. 108. Establishment of health care fraud and abuse data base.
- Sec. 109. Definitions.
- Sec. 110. Effective date.

TITLE II—REVISIONS TO CRIMINAL LAW

- Sec. 201. Definition of Federal health care offense.
- Sec. 202. Health care fraud.
- Sec. 203. Theft or embezzlement.
- Sec. 204. False Statements.
- Sec. 205. Bribery and graft.
- Sec. 206. Illegal remuneration with respect to health care benefit programs.
- Sec. 207. Obstruction of criminal investigations of health care offenses.
- Sec. 208. Civil penalties for violations of Federal health care offenses.
- Sec. 209. Injunctive relief relating to health care offenses.
- Sec. 210. Authorized investigative demand procedures.
- Sec. 211. Grand jury disclosure.
- Sec. 212. Miscellaneous amendments to title 18, United States code.

TITLE III—ANTI-FRAUD INITIATIVES UNDER MEDICARE AND
MEDICAID

- Sec. 301. Revision to current penalties.
- Sec. 302. Solicitation and publication of modifications to existing safe harbors and new safe harbors; additional exception for certain discounting and managed care arrangements.
- Sec. 303. Expediting implementation of payment adjustments for durable medical equipment based upon inherent reasonableness.
- Sec. 304. Requiring annual notice to medicare beneficiaries of need to prevent fraud and abuse against medicare program.
- Sec. 305. Requiring use of single provider number in submission of claims for payment under medicare and medicaid.
- Sec. 306. Liability of carriers and fiscal intermediaries for claims submitted by excluded providers.
- Sec. 307. Requiring fiscal intermediaries and carriers to use automated data processing equipment comparable to equipment used in private insurance business.
- Sec. 308. Nondischargeability under bankruptcy code of amounts owed for overpayments.

TITLE I—COORDINATION OF FEDERAL ENFORCEMENT

SEC. 101. FEDERAL ENFORCEMENT BY INSPECTORS GENERAL AND ATTORNEY GENERAL.

(a) AUDITS, INVESTIGATIONS, INSPECTIONS, AND EVALUATIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Inspector General of each of the Department of Health and Human Services, the Department of Defense, the Department of Labor, the Office of Personnel Management, and the Department of Veterans Affairs, and the Attorney General shall conduct audits, civil and criminal investigations, inspections, and evaluations relating to the prevention, detection, and control of health care fraud and abuse in violation of any Federal law.

(2) LIMITATION.—An Inspector General, other than the Inspector General of the Department of Health and Human Services, may not conduct any audit, investigation, inspection, or evaluation under paragraph (1) with respect to health care fraud or abuse under title V, XI, XVIII, XIX, or XX of the Social Security Act.

(b) POWERS.—For purposes of carrying out duties and responsibilities under subsection (a), each Inspector

1 General referred to in subsection (a) may exercise powers
2 that are available to the Inspector General for purposes
3 of audits, investigations, and other activities under the In-
4 spector General Act of 1978 (5 U.S.C. App.).

5 (c) COORDINATION AND REVIEW OF ACTIVITIES OF
6 OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—

7 (1) PROGRAM.—The Inspector General and the
8 Attorney General shall—

9 (A) jointly establish, on the effective date
10 specified in section 110(a), a program to pre-
11 vent, detect, and control health care fraud and
12 abuse in violation of any Federal law, which
13 takes into account the activities of Federal,
14 State, and local law enforcement agencies, Fed-
15 eral and State agencies responsible for the li-
16 censing and certification of health care provid-
17 ers, and State agencies designated under sec-
18 tion 102(a)(1); and

19 (B) publish a description of the program in
20 the Federal Register, by not later than 180
21 days after the date of the enactment of this
22 Act.

23 (2) ANNUAL INVESTIGATIVE PLAN.—Each In-
24 spector General referred to in subsection (a)(1) and
25 the Attorney General shall each develop an annual

1 investigative plan for the prevention, detection, and
2 control of health care fraud and abuse in accordance
3 with the program established under paragraph (1).

4 (d) CONSULTATIONS.—Each of the Inspectors Gen-
5 eral referred to in subsection (a)(1) and the Attorney Gen-
6 eral shall regularly consult with each other, with Federal,
7 State, and local law enforcement agencies, with Federal
8 and State agencies responsible for the licensing and cer-
9 tification of health care providers, and with Health Care
10 Fraud and Abuse Control Units, in order to assist in co-
11 ordinating the prevention, detection, and control of health
12 care fraud and abuse in violation of any federal law.

13 **SEC. 102. STATE ENFORCEMENT.**

14 (a) DESIGNATION OF STATE AGENCIES AND ESTAB-
15 LISHMENT OF HEALTH CARE FRAUD AND ABUSE CON-
16 TROL UNIT.—The Governor of each State—

17 (1) shall, consistent with State law, designate
18 agencies of the State which conduct, supervise, and
19 coordinate audits, civil and criminal investigations,
20 inspections, and evaluations relating to the preven-
21 tion, detection, and control of health care fraud and
22 abuse in violation of any Federal law in the State;
23 and

24 (2) may establish and maintain in accordance
25 with subsection (b) a State agency to act as a

1 Health Care Fraud and Abuse Control Unit for pur-
2 poses of this title.

3 (b) HEALTH CARE FRAUD AND ABUSE CONTROL
4 UNIT REQUIREMENTS.—A Health Care Fraud and Abuse
5 Control Unit established by a State under subsection
6 (a)(2) shall be a single identifiable entity of State govern-
7 ment which is separate and distinct from any State agency
8 with principal responsibility for the administration of
9 health care programs, and which meets the following re-
10 quirements:

11 (1) The entity—

12 (A) is a unit of the office of the State At-
13 torney General or of another department of
14 State government that possesses statewide au-
15 thority to prosecute individuals for criminal vio-
16 lations;

17 (B) is in a State the constitution of which
18 does not provide for the criminal prosecution of
19 individuals by a statewide authority, and has
20 formal procedures, approved by the Secretary,
21 that assure it will refer suspected criminal vio-
22 lations relating to health care fraud or abuse in
23 violation of any Federal law to the appropriate
24 authority or authorities of the State for pros-

1 ecution and assure it will assist such authority
2 or authorities in such prosecutions; or

3 (C) has a formal working relationship with
4 the office of the State Attorney General or the
5 appropriate authority or authorities for pros-
6 ecution and has formal procedures (including
7 procedures under which it will refer suspected
8 criminal violations to such office), that provide
9 effective coordination of activities between the
10 Health Care Fraud and Abuse Control Unit
11 and such office with respect to the detection, in-
12 vestigation, and prosecution of suspected health
13 care fraud or abuse in violation of any Federal
14 law.

15 (2) The entity conducts a statewide program
16 for the investigation and prosecution of violations of
17 all applicable State laws regarding any and all as-
18 pects of health care fraud and abuse under Federal
19 law.

20 (3) The entity has procedures for—

21 (A) reviewing complaints of the abuse or
22 neglect of patients of health care facilities in
23 the State, and

24 (B) where appropriate, investigating and
25 prosecuting such complaints under the criminal

1 laws of the State or for referring the complaints
2 to other State or Federal agencies for action.

3 (4) The entity provides for the collection, or re-
4 ferral for collection to the appropriate agency, of
5 overpayments that—

6 (A) are made under any federally funded
7 or mandated health care program required by
8 this Act, and

9 (B) it discovers in carrying out its activi-
10 ties.

11 (5) The entity employs attorneys, auditors, in-
12 vestigators, and other necessary personnel, is orga-
13 nized in such a manner, and provides sufficient re-
14 sources, as is necessary to promote the effective and
15 efficient conduct of its activities.

16 (c) SUBMISSION OF ANNUAL PLAN.—Each Health
17 Care Fraud and Abuse Control Unit may submit each year
18 to the Inspector General and the Attorney General a plan
19 for preventing, detecting, and controlling, consistent with
20 the program established under section 101(c)(1), health
21 care fraud and abuse in violation of any Federal law.

22 (d) APPROVAL OF ANNUAL PLAN.—The Inspector
23 General shall approve a plan submitted under subsection
24 (c) by the Health Care Fraud and Abuse Control Unit

1 of a State, unless the Inspector General establishes that
2 the plan—

3 (1) is inconsistent with the program established
4 under section 101(c)(1); or

5 (2) will not enable the agencies of the State
6 designated under subsection (a)(1) to prevent, de-
7 tect, and control health care fraud and abuse in vio-
8 lation of any Federal law.

9 (e) REPORTS.—Each Health Care Fraud and Abuse
10 Control Unit shall submit to the Inspector General an an-
11 nual report containing such information as the Inspector
12 General determines to be necessary.

13 (f) SEMIANNUAL REPORTS OF INSPECTOR GENERAL
14 OF HEALTH AND HUMAN SERVICES.—The Inspector Gen-
15 eral shall include in its semiannual reports to the Congress
16 under section 5(a) of the Inspector General Act of 1978
17 (5 U.S.C. App.) an assessment of the Inspector General
18 of the effectiveness of States in preventing, detecting, and
19 controlling health care fraud and abuse.

20 **SEC. 103. PAYMENTS TO STATES.**

21 (a) IN GENERAL.—For each year for which a State
22 has an annual plan approved under section 102(d), and
23 subject to the availability of appropriations, the Inspector
24 General shall pay to the State for each quarter an amount
25 equal to 75 percent of the sums expended during the quar-

1 ter by agencies designated by the Governor of the State
 2 under section 102(a)(1) in conducting activities described
 3 in that subsection.

4 (b) TIME OF PAYMENT.—The Inspector General shall
 5 make a payment under subsection (a) for a quarter by
 6 not later than 30 days after the end of the quarter.

7 (c) PAYMENTS ARE ADDITIONAL.—Payments to a
 8 State under this subsection shall be in addition to any
 9 amounts paid under section 106.

10 **SEC. 104. HEALTH CARE FRAUD AND ABUSE CONTROL AC-**
 11 **COUNT.**

12 (a) ESTABLISHMENT.—There is established on the
 13 books of the Treasury of the United States a separate ac-
 14 count, which shall be known as the Health Care Fraud
 15 and Abuse Control Account. The Account shall consist
 16 of—

17 (1) the Health Care Fraud and Abuse Expenses
 18 Subaccount; and

19 (2) the Health Care Fraud and Abuse Reserve
 20 Subaccount.

21 (b) EXPENSES SUBACCOUNT.—

22 (1) CONTENTS.—The Expenses Subaccount
 23 consists of—

24 (A) amounts deposited under paragraph
 25 (2); and

1 (B) amounts transferred from the Reserve
2 Subaccount under subsection (c)(2).

3 (2) DEPOSITS.—Except as provided in sub-
4 section (c)(1), there shall be deposited in the Ex-
5 penses Subaccount all amounts received by the Unit-
6 ed States as—

7 (A) fines imposed in cases involving a Fed-
8 eral health care offense;

9 (B) civil penalties or damages (other than
10 restitution) in actions under section 3729 or
11 3730 of title 31, United States Code (commonly
12 referred to as the “False Claims Act”), that are
13 based on claims related to the provision of
14 health care items and services;

15 (C) administrative penalties under titles
16 XI, XVIII, and XIX of the Social Security Act;

17 (D) proceeds of seizures and forfeitures of
18 property for acts or omissions in violation of
19 any Federal law related to the provision of
20 health care items and services; and

21 (E) money and proceeds of property that
22 are accepted under section 105.

23 (3) USE.—Amounts in the Expenses Sub-
24 account shall be available to the Inspector General
25 and the Attorney General, under such terms and

conditions as the Inspector General and the Attorney General jointly determine to be appropriate, for—

(A) paying expenses incurred by their respective agencies in carrying out activities under section 101; and

(B) making reimbursements to other Inspectors General and Federal, State, and local agencies in accordance with section 106.

(c) RESERVE SUBACCOUNT.—

(1) DEPOSITS.—An amount otherwise required under subsection (b)(1) to be deposited in the Expenses Subaccount in a fiscal year shall be deposited in the Reserve Subaccount, if—

(A) the amount in the Expenses Subaccount is greater than \$500,000,000; and

(B) the deposit of that amount in the Expenses Subaccount would result in the amount in the Expenses Subaccount exceeding 110 percent of the total amount deposited in the Expenses Subaccount in the preceding fiscal year.

(2) TRANSFERS TO EXPENSES SUBACCOUNT.—

(A) ESTIMATION OF SHORTFALL.—Not later than the first day of the last quarter of each fiscal year, the Inspector General (in con-

sultation with the Attorney General) shall estimate whether sufficient amounts will be available during such quarter in the Expenses Subaccount for the uses described in subsection (b)(3).

(B) TRANSFER TO COVER SHORTFALL.—If the Inspector General estimates under subsection (a) that there will not be available sufficient amounts in the Expenses Subaccount during the last quarter of a fiscal year, there shall be transferred from the Reserve Subaccount to the Expenses Subaccount such amount as the Inspector General estimates is required to ensure that sufficient amounts are available in the Expenses Subaccount during such quarter.

(3) LIMITATION ON AMOUNT CARRIED OVER TO SUCCEEDING FISCAL YEAR.—There shall be transferred to the general fund of the Treasury any amount remaining in the Reserve Subaccount at the end of a fiscal year (after any transfer made under paragraph (2)) in excess of 10 percent of the total amount authorized to be deposited in the Expenses Subaccount (consistent with paragraph (1)) during the fiscal year.

1 (d) ANNUAL REPORT TO CONGRESS.—Not later than
2 180 days after the end of each fiscal year (beginning with
3 fiscal year 1997), the Secretary of Health and Human
4 Services and the Attorney General shall submit a report
5 to the Committee on Government Reform and Oversight
6 of the House of Representatives and the Committee on
7 Governmental Affairs of the Senate on the operations of
8 the Account during the fiscal year, including a description
9 of the deposits made into the Account and the payments
10 made from the Account during the year.

11 **SEC. 105. ACCEPTANCE OF GIFTS, BEQUESTS, AND DEVISES.**

12 The Attorney General or any Inspector General re-
13 ferred to in section 101(a) may accept, use, and dispose
14 of gifts, bequests, or devises of services or property (real
15 or personal), for the purpose of aiding or facilitating ac-
16 tivities under this title regarding health care fraud and
17 abuse. Gifts, bequests, or devises of money and proceeds
18 from sales of other property received as gifts, bequests,
19 or devises shall be deposited in the Account and shall be
20 available for use in accordance with section 104(b)(3).

21 **SEC. 106. REIMBURSEMENTS OF EXPENSES AND OTHER**
22 **PAYMENTS TO PARTICIPATING AGENCIES.**

23 (a) REIMBURSEMENT OF EXPENSES OF FEDERAL
24 AGENCIES.—The Inspector General and the Attorney
25 General, subject to the availability of amounts in the Ac-

1 count, shall jointly and promptly reimburse Federal agen-
2 cies for expenses incurred in carrying out section 101.

3 (b) PAYMENTS TO STATE AND LOCAL LAW EN-
4 FORCEMENT AGENCIES.—The Inspector General and the
5 Attorney General, subject to the availability of amounts
6 in the Account, shall jointly and promptly pay to any State
7 or local law enforcement agency that participated directly
8 in any activity which led to deposits in the Account, or
9 property the proceeds of which are deposited in the Ac-
10 count, an amount that reflects generally and equitably the
11 participation of the agency in the activity.

12 (c) FUNDS USED TO SUPPLEMENT AGENCY APPRO-
13 PRIATIONS.—It is intended that disbursements made from
14 the Account to any Federal agency be used to increase
15 and not supplant the recipient agency's appropriated oper-
16 ating budget.

17 **SEC. 107. ACCOUNT PAYMENTS ADVISORY BOARD.**

18 (a) ESTABLISHMENT.—There is established the Ac-
19 count Payments Advisory Board, which shall make rec-
20 ommendations to the Inspector General and the Attorney
21 General regarding the equitable allocation of payments
22 from the Account.

23 (b) MEMBERSHIP.—The Board shall consist of—

24 (1) each of the Inspectors General referred to
25 in section 101(a), other than the Inspector General

1 of the Department of Health and Human Services;
2 and

3 (2) 10 members appointed by the Inspector
4 General of the Department of Health and Human
5 Services to represent Health Care Fraud and Abuse
6 Control Units, of whom one shall be appointed—

7 (A) for each of the 10 regions established
8 by the Director of the Office of Management
9 and Budget under Office of Management and
10 Budget Circular A-105, to represent Units in
11 that region; and

12 (B) from among individuals recommended
13 by the heads of those agencies in that region.

14 (c) TERMS.—The term of a Member of the Board ap-
15 pointed under subsection (b)(2) shall be 3 years, except
16 that of such members first appointed 3 members shall
17 serve an initial term of one year and 3 members shall serve
18 an initial term of 2 years, as specified by the Inspector
19 General at the time of appointment.

20 (d) VACANCIES.—A vacancy on the Board shall be
21 filled in the same manner in which the original appoint-
22 ment was made, except that an individual appointed to
23 fill a vacancy occurring before the expiration of the term
24 for which the individual is appointed shall be appointed
25 only for the remainder of that term.

1 (e) CHAIRPERSON AND BYLAWS.—The Board shall
2 elect one of its members as chairperson and shall adopt
3 bylaws.

4 (f) COMPENSATION AND EXPENSES.—Members of
5 the Board shall serve without compensation, except that
6 the Inspector General may pay the expenses reasonably
7 incurred by the Board in carrying out its functions under
8 this section.

9 (g) NO TERMINATION.—Section 14(a)(2) of the Fed-
10 eral Advisory Committee Act (5 U.S.C. App.) does not
11 apply to the Board.

12 **SEC. 108. ESTABLISHMENT OF HEALTH CARE FRAUD AND**
13 **ABUSE DATA BASE.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services, in consultation with the Attorney Gen-
16 eral, shall establish a data base for the reporting of final
17 adverse actions taken by a Government agency against
18 health care providers, suppliers, or practitioners, or
19 against health care benefit programs, in order to provide
20 a central repository of such information to assist in the
21 prevention, detection, and prosecution of health care fraud
22 and abuse.

23 (b) REPORTING INFORMATION.—

24 (1) IN GENERAL.—For purposes of establishing
25 and maintaining the data base under this section,

1 each Government agency shall report any final ad-
2 verse action taken against a health care provider,
3 supplier, or practitioner, or against a health care
4 benefit program, together with the information de-
5 scribed in paragraph (2).

6 (2) INFORMATION TO BE REPORTED.—The in-
7 formation referred to in this paragraph is as follows:

8 (A) The name of any health care insurer,
9 provider, supplier, or practitioner or health care
10 benefit program which is the subject of the final
11 adverse action reported under paragraph (1).

12 (B) In the case of a final adverse action
13 taken against a health care provider, supplier,
14 or practitioner, the name (if known) of any
15 health care benefit program with which the in-
16 surer, provider, supplier, or practitioner is af-
17 filiated or associated.

18 (C) The nature of the final adverse action.

19 (D) A description of the acts or omissions
20 and injuries upon which the final adverse action
21 was based.

22 (E) Such other information as required by
23 the Secretary.

24 (3) CONFIDENTIALITY.—The Secretary shall es-
25 tablish procedures to assure that in the submission

19

1 of information under this subsection the privacy of
2 individuals receiving health care services is appro-
3 priately protected.

4 (4) FORM AND MANNER OF REPORTING.—The
5 information required to be reported under this sub-
6 section shall be reported on a monthly basis and in
7 such form and manner as determined by the Sec-
8 retary. Such information shall first be required to be
9 reported on a date specified by the Secretary.

10 (5) TO WHOM REPORTED.—The information re-
11 quired to be reported under this subsection shall be
12 reported to the Secretary or such person or persons
13 designated by the Secretary.

14 (c) CORRECTION OF ERRONEOUS INFORMATION.—

15 (1) DISCLOSURE AND CORRECTION.—The Sec-
16 retary shall provide for a procedure through which
17 a person, to whom information within the data base
18 established under this section pertains, may review
19 that information and obtain the correction of errors
20 pertaining to that person.

21 (2) OTHER CORRECTIONS.—Each Government
22 agency shall report corrections of information al-
23 ready reported about any final adverse action taken
24 against a health care provider, supplier, or practi-

20

1 tioner, or a health care benefit program, in such
2 form and manner as required by the Secretary.

3 (d) ACCESS TO REPORTED INFORMATION.—

4 (1) AVAILABILITY.—The information in this
5 data base shall be available to the public, Federal
6 and State law enforcement agencies, Federal and
7 State government agencies, and health care benefit
8 programs pursuant to procedures established by the
9 Secretary and Attorney General.

10 (2) FEES.—The Secretary may establish rea-
11 sonable fees for the disclosure of information in this
12 data base.

13 (e) PROTECTION FROM LIABILITY FOR REPORT-
14 ING.—No person may be held liable in any civil action with
15 respect to reporting information required to be reported
16 under this section, unless the information reported was
17 false and the person had knowledge of the falsity of the
18 information.

19 (f) DEFINITIONS AND SPECIAL RULES.—For pur-
20 poses of this section:

21 (1) The term “final adverse action” includes
22 the following:

23 (A) Civil judgments in Federal or State
24 court related to the delivery of a health care
25 item or service.

(B) Federal or State criminal convictions related to the delivery of a health care item or service, as determined in accordance with procedures applicable to the exclusion of individuals and entities under section 1128(j) of the Social Security Act.

(C) Actions by State or Federal agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners, including—

(i) formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation;

(ii) any other loss of license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender or otherwise; or

(iii) any other negative action or finding by such State or Federal agency that is publicly available information.

(D) Exclusion from participation in Federal or State health care programs.

(E) Any other actions as required by the Secretary.

1 (2) The term "Government agency" includes—

2 (A) the Department of Justice;

3 (B) the Department of Health and Human
4 Services;

5 (C) any other Federal agency that either
6 administers or provides payment for the deliv-
7 ery of health care services, including (but not
8 limited to) the Department of Defense and the
9 Department of Veterans Affairs;

10 (D) State law enforcement agencies;

11 (E) State Medicaid fraud and abuse con-
12 trol units described in section 1903(q) of the
13 Social Security Act; and

14 (F) State or Federal agencies responsible
15 for the licensing and certification of health care
16 providers and licensed health care practitioners.

17 (3) The term "health care benefit program" has
18 the meaning given such term in section 1347(b) of
19 title 18, United States Code, as added by section
20 202(b).

21 (4) The term "health care provider" means a
22 provider of services (as defined in section 1861(u) of
23 the Social Security Act) and any entity, including a
24 health maintenance organization or group medical

1 practice, that provides health care services (as speci-
2 fied by the Secretary in regulations).

3 (5) The terms "licensed health care practi-
4 tioner" and "practitioner" mean, with respect to a
5 State, an individual who is licensed or otherwise au-
6 thorized by the State to provide health care services
7 (or any individual who without authority holds him-
8 self or herself out to be so licensed or authorized).

9 (6) The term "Secretary" means the Secretary
10 of Health and Human Services.

11 (7) The term "supplier" means a supplier of
12 items and services for which payment may be made
13 under part B of title XVIII of the Social Security
14 Act.

15 **SEC. 109. DEFINITIONS.**

16 In this title:

17 (1) **ACCOUNT.**—The term "Account" means the
18 Health Care Fraud and Abuse Control Account es-
19 tablished by section 104(a).

20 (2) **EXPENSES SUBACCOUNT.**—The term "Ex-
21 penses Subaccount" means the Health Care Fraud
22 and Abuse Expenses Subaccount of the Account.

23 (3) **FEDERAL HEALTH CARE OFFENSE.**—The
24 term "Federal health care offense" has the meaning

1 given such term in section 24(a) of title 18, United
2 States Code.

3 (4) HEALTH CARE FRAUD AND ABUSE CONTROL
4 UNIT.—The term “Health Care Fraud and Abuse
5 Control Unit” means such a unit established by a
6 State in accordance with section 102(b).

7 (5) INSPECTOR GENERAL.—Except as otherwise
8 provided, the term “Inspector General” means the
9 Inspector General of the Department of Health and
10 Human Services.

11 (6) RESERVE SUBACCOUNT.—The term “Re-
12 serve Subaccount” means the Health Care Fraud
13 and Abuse Reserve Subaccount of the Account.

14 **SEC. 110. EFFECTIVE DATE.**

15 (a) IN GENERAL.—Except as provided in subsection
16 (b), this title shall take effect after the expiration of the
17 180-day period which begins on the date of the enactment
18 of this Act.

19 (b) DEVELOPMENT AND PUBLICATION OF DESCRIP-
20 TION OF PROGRAM.—Section 101(c)(1) shall take effect
21 on the date of the enactment of this Act.

TITLE II—REVISIONS TO CRIMINAL LAW

SEC. 201. DEFINITION OF FEDERAL HEALTH CARE OFFENSE.

(a) IN GENERAL.—Chapter 2 of title 18, United States Code, is amended by adding at the end the following:

“§ 24. Definition of Federal health care offense

“(a) As used in this title, the term ‘Federal health care offense’ means—

“(1) a violation of, or criminal conspiracy to violate section 226, 227, 669, 1035, 1347, or 1518 of this title;

“(2) a violation of, or criminal conspiracy to violate section 1128B of the Social Security Act (42 U.S.C. 1320a-7b);

“(3) a violation of, or criminal conspiracy to violate section 201, 287, 371, 664, 666, 1001, 1027, 1341, 1343, or 1954 of this title, if the violation or conspiracy relates to a health care benefit program;

“(4) a violation of, or criminal conspiracy to violate section 411, 501, or 511 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1111; 29 U.S.C. 1131; 29 U.S.C. 1141), if the viola-

1 tion or conspiracy relates to a health care benefit
2 program; or

3 “(5) a violation of, or criminal conspiracy to
4 violate, section 3 of the Anti-Kickback Act of 1986
5 (41 U.S.C. 53), if the violation or conspiracy relates
6 to a health care benefit program.

7 “(b) As used in this title, the term ‘health care bene-
8 fit program’ has the meaning given such term in section
9 1347(b) of this title.”.

10 (b) CLERICAL AMENDMENT.—The table of sections
11 at the beginning of chapter 2 of title 18, United States
12 Code, is amended by inserting after the item relating to
13 section 23 the following new item:

“24. Definition relating to Federal health care offense defined.”.

14 **SEC. 202. HEALTH CARE FRAUD.**

15 (a) IN GENERAL.—Chapter 63 of title 18, United
16 States Code, is amended by adding at the end the follow-
17 ing:

18 **“§ 1347. Health care fraud**

19 “(a) Whoever, having devised or intending to devise
20 a scheme or artifice, commits or attempts to commit an
21 act in furtherance of or for the purpose of executing such
22 scheme or artifice—

23 “(1) to defraud any health care benefit pro-
24 gram; or

1 “(2) to obtain, by means of false or fraudulent
 2 pretenses, representations, or promises, any of the
 3 money or property owned by, or under the custody
 4 or control of, any health care benefit program,
 5 shall be fined under this title or imprisoned not more than
 6 10 years, or both. If the violation results in serious bodily
 7 injury (as defined in section 1365 of this title), such per-
 8 son shall be fined under this title or imprisoned not more
 9 than 20 years, or both; and if the violation results in
 10 death, such person shall be fined under this title, or im-
 11 prisoned for any term of years or for life, or both.

12 “(b) As used in this section, the term ‘health care
 13 benefit program’ means any public or private plan or con-
 14 tract under which any medical benefit, item, or service is
 15 provided to any individual, and includes any individual or
 16 entity who is providing a medical benefit, item, or service
 17 for which payment may be made under the plan or con-
 18 tract.”.

19 (b) CLERICAL AMENDMENT.—The table of sections
 20 at the beginning of chapter 63 of title 18, United States
 21 Code, is amended by adding at the end the following:

“1347. Health care fraud.”.

22 **SEC. 203. THEFT OR EMBEZZLEMENT.**

23 (a) IN GENERAL.—Chapter 31 of title 18, United
 24 States Code, is amended by adding at the end the follow-
 25 ing:

1 **“§ 669. Theft or embezzlement in connection with**
 2 **health care**

3 “(a) Whoever embezzles, steals, or otherwise without
 4 authority willfully and unlawfully converts to the use of
 5 any person other than the rightful owner, or intentionally
 6 misapplies any of the moneys, funds, securities, premiums,
 7 credits, property, or other assets of a health care benefit
 8 program, shall be fined under this title or imprisoned not
 9 more than 10 years, or both.

10 “(b) As used in this section, the term ‘health care
 11 benefit program’ has the meaning given such term in sec-
 12 tion 1347(b) of this title.”.

13 (b) CLERICAL AMENDMENT.—The table of sections
 14 at the beginning of chapter 31 of title 18, United States
 15 Code, is amended by adding at the end the following:

“669. Theft or embezzlement in connection with health care.”.

16 **SEC. 204. FALSE STATEMENTS.**

17 (a) IN GENERAL.—Chapter 47 of title 18, United
 18 States Code, is amended by adding at the end the follow-
 19 ing:

20 **“§ 1035. False statements relating to health care mat-**
 21 **ters**

22 “(a) Whoever, in any matter involving a health care
 23 benefit program, knowingly and willfully falsifies, conceals,
 24 or covers up by any trick, scheme, or device a material
 25 fact, or makes any false, fictitious, or fraudulent state-

1 ments or representations, or makes or uses any false writ-
 2 ing or document knowing the same to contain any false,
 3 fictitious, or fraudulent statement or entry, shall be fined
 4 under this title or imprisoned not more than 5 years, or
 5 both.

6 “(b) As used in this section, the term ‘health care
 7 benefit program’ has the meaning given such term in sec-
 8 tion 1347(b) of this title.”.

9 (b) CLERICAL AMENDMENT.—The table of sections
 10 at the beginning of chapter 47 of title 18, United States
 11 Code, is amended by adding at the end the following new
 12 item:

“1035. False statements relating to health care matters.”.

13 **SEC. 205. BRIBERY AND GRAFT.**

14 (a) IN GENERAL.—Chapter 11 of title 18, United
 15 States Code, is amended by adding at the end the follow-
 16 ing:

17 **“§ 226. Bribery and graft in connection with health**
 18 **care**

19 “(a) Whoever—

20 “(1) directly or indirectly, corruptly gives, of-
 21 fers, or promises anything of value to a health care
 22 official, or offers or promises to give anything of
 23 value to any other person, or attempts to violate this
 24 subsection, with intent—

1 “(A) to influence any of the health care of-
2 ficial’s actions, decisions, or duties relating to a
3 health care benefit program;

4 “(B) to influence such an official to com-
5 mit or aid in the committing, or collude in or
6 allow, any fraud, or make opportunity for the
7 commission of any fraud, on a health care bene-
8 fit program; or

9 “(C) to induce such an official to engage
10 in any conduct in violation of the lawful duty of
11 such official; or

12 “(2) being a health care official, directly or in-
13 directly, corruptly demands, seeks, receives, accepts,
14 or agrees to accept anything of value personally or
15 for any other person or entity, the giving of which
16 violates paragraph (1) of this subsection, or at-
17 tempts to violate this subsection,

18 shall be fined under this title or imprisoned not more than
19 15 years, or both.

20 “(b) Whoever—

21 “(1) otherwise than as provided by law for the
22 proper discharge of any duty, directly or indirectly
23 gives, offers, or promises anything of value to a
24 health care official, for or because of any of the
25 health care official’s actions, decisions, or duties re-

1 lating to a health care benefit program, or attempts
2 to violate this subsection; or

3 “(2) being a health care official, otherwise than
4 as provided by law for the proper discharge of any
5 duty, directly or indirectly, demands, seeks, receives,
6 accepts or agrees to accept anything of value person-
7 ally or for any other person or entity, the giving of
8 which violates paragraph (1) of this subsection, or
9 attempts to violate this subsection,

10 shall be fined under this title, or imprisoned not more than
11 2 years, or both.

12 “(c) As used in this section—

13 “(1) the term ‘health care official’ means—

14 “(A) an administrator, officer, trustee, fi-
15 duciary, custodian, counsel, agent, or employee
16 of any health care benefit program;

17 “(B) an officer, counsel, agent, or em-
18 ployee, of an organization that provides services
19 under contract to any health care benefit pro-
20 gram; or

21 “(C) an official, employee, or agent of an
22 entity having regulatory authority over any
23 health care benefit program; and

1 “(2) the term ‘health care benefit program’ has
2 the meaning given such term in section 1347(b) of
3 this title.”.

4 (b) CLERICAL AMENDMENT.—The table of chapters
5 at the beginning of chapter 11 of title 18, United States
6 Code, is amended by adding at the end the following new
7 item:

 “226. Bribery and graft in connection with health care.”.

8 **SEC. 206. ILLEGAL REMUNERATION WITH RESPECT TO**
9 **HEALTH CARE BENEFIT PROGRAMS.**

10 (a) IN GENERAL.—Chapter 11 of title 18, United
11 States Code, is amended by adding at the end the follow-
12 ing:

13 **“§227. Illegal remuneration with respect to health**
14 **care benefit programs**

15 “(a) Whoever knowingly and willfully solicits or re-
16 ceives any remuneration (including any kickback, bribe, or
17 rebate) directly or indirectly, overtly or covertly, in cash
18 or in kind—

19 “(1) in return for referring any individual to a
20 person for the furnishing or arranging for the fur-
21 nishing of any item or service for which payment
22 may be made in whole or in part by any health care
23 benefit program; or

24 “(2) in return for purchasing, leasing, ordering,
25 or arranging for or recommending purchasing, leas-

ing, or ordering any good, facility, service, or item
for which payment may be made in whole or in part
by any health care benefit program, or attempting to
do so,

shall be fined under this title or imprisoned for not more
than 5 years, or both.

“(b) Whoever knowingly and willfully offers or pays
any remuneration (including any kickback, bribe, or re-
bate) directly or indirectly, overtly, or covertly, in cash or
in kind to any person to induce such person—

“(1) to refer an individual to a person for the
furnishing or arranging for the furnishing of any
item or service for which payment may be made in
whole or in part by any health benefit program; or

“(2) to purchase, lease, order, or arrange for or
recommend purchasing, leasing, or ordering any
good, facility, service, or item for which payment
may be made in whole or in part by any health bene-
fit program or attempts to do so,

shall be fined under this title or imprisoned for not more
than 5 years, or both.

“(c) Subsections (a) and (b) shall not apply to—

“(1) a discount or other reduction in price ob-
tained by a provider of services or other entity under
a health care benefit program if the reduction in

1 price is properly disclosed and appropriately re-
2 flected in the costs claimed or charges made by the
3 provider or entity under a health care benefit pro-
4 gram;

5 “(2) any amount paid by an employer to an em-
6 ployee (who has a bona fide employment relationship
7 with such employer) for employment in the provision
8 of covered items or services if the amount of the re-
9 muneratation under the arrangement is consistent
10 with the fair market value of the services and is not
11 determined in a manner that takes into account (di-
12 rectly or indirectly) the volume or value of any refer-
13 rals;

14 “(3) any amount paid by a vendor of goods or
15 services to a person authorized to act as a purchas-
16 ing agent for a group of individuals or entities who
17 are furnishing services reimbursed under a health
18 care benefit program if—

19 “(A) the person has a written contract,
20 with each such individual or entity, which speci-
21 fies the amount to be paid the person, which
22 amount may be a fixed amount or a percentage
23 of the value of the purchases made by each
24 such individual or entity under the contract,
25 and

“(B) in the case of an entity that is a provider of services (as defined in section 1861(u) of the Social Security Act, the person discloses (in such form and manner as the Secretary of Health and Human Services requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

“(4) a waiver of any coinsurance under part B of title XVIII of the Social Security Act by a federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act; and

“(5) any payment practice specified by the Secretary of Health and Human Services in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987.

“(d) Any person injured in his business or property by reason of a violation of this section or section 226 of this title may sue therefor in any appropriate United States district court and shall recover threefold the damages such person sustains and the cost of the suit, including a reasonable attorney’s fee.

1 “(e) As used in this section, ‘health care benefit pro-
2 gram’ has the meaning given such term in section 1347(b)
3 of this title.”.

4 (b) CLERICAL AMENDMENT.—The table of sections
5 at the beginning of chapter 11 of title 18, United States
6 Code, is amended by adding at the end the following:

“227. Illegal remuneration with respect to health care benefit programs.”.

7 (c) CONFORMING AMENDMENT.—Section 1128B of
8 the Social Security Act (42 U.S.C. 1320a-7b) is amended
9 by striking subsection (b).

10 **SEC. 207. OBSTRUCTION OF CRIMINAL INVESTIGATIONS OF**
11 **HEALTH CARE OFFENSES.**

12 (a) IN GENERAL.—Chapter 73 of title 18, United
13 States Code, is amended by adding at the end the follow-
14 ing:

15 **“§ 1518. Obstruction of criminal investigations of**
16 **health care offenses**

17 “(a) Whoever willfully prevents, obstructs, misleads,
18 delays or attempts to prevent, obstruct, mislead, or delay
19 the communication of information or records relating to
20 a violation of a health care offense to a criminal investiga-
21 tor shall be fined under this title or imprisoned not more
22 than 5 years, or both.

23 “(b) As used in this section the term ‘health care of-
24 fense’ has the meaning given such term in section 24 of
25 this title.

1 “(c) As used in this section the term ‘criminal inves-
2 tigator’ means any individual duly authorized by a depart-
3 ment, agency, or armed force of the United States to con-
4 duct or engage in investigations for prosecutions for viola-
5 tions of health care offenses.”.

6 (b) CLERICAL AMENDMENT.—The table of sections
7 at the beginning of chapter 73 of title 18, United States
8 Code, is amended by adding at the end the following new
9 item:

“1518. Obstruction of criminal investigations of health care offenses.”.

10 **SEC. 208. CIVIL PENALTIES FOR VIOLATIONS OF FEDERAL**
11 **HEALTH CARE OFFENSES.**

12 (a) IN GENERAL.—Chapter 63 of title 18, United
13 States Code, is amended by adding at the end the follow-
14 ing:

15 **“§ 1348. Civil penalties for violations of Federal**
16 **health care offenses**

17 “The Attorney General may bring a civil action in
18 the appropriate United States district court against any
19 person who engages in conduct constituting a Federal
20 health care offense, as that term is defined in section 24
21 of this title and, upon proof of such conduct by a prepon-
22 derance of the evidence, such person shall be subject to
23 a civil penalty of not more than 3 times the amount of
24 compensation or proceeds which the person received or of-
25 fered for the prohibited conduct. The imposition of a civil

1 penalty under this section does not preclude any other
2 criminal or civil statutory, common law, or administrative
3 remedy, which is available by law to the United States or
4 any other person.”.

5 (b) CLERICAL AMENDMENT.—The table of sections
6 for chapter 63 of title 18, United States Code, is amended
7 by adding at the end the following item:

“1348. Civil penalties for violations of Federal health care offenses.”.

8 **SEC. 209. INJUNCTIVE RELIEF RELATING TO HEALTH CARE**
9 **OFFENSES.**

10 (a) IN GENERAL.—Section 1345(a)(1) of title 18,
11 United States Code, is amended—

12 (1) by striking “or” at the end of subparagraph
13 (A);

14 (2) by inserting “or” at the end of subpara-
15 graph (B); and

16 (3) by adding at the end the following:

17 “(C) committing or about to commit a
18 Federal health care offense (as defined in sec-
19 tion 24 of this title).”.

20 (b) FREEZING OF ASSETS.—Section 1345(a)(2) of
21 title 18, United States Code, is amended by inserting “or
22 a Federal health care offense (as defined in section 24)”
23 after “title”).

1 SEC. 210. AUTHORIZED INVESTIGATIVE DEMAND PROCE-
2 DURES.

3 (a) IN GENERAL.—(Chapter 223 of title 18, United
4 States Code, is amended by adding after section 3485 the
5 following:

6 “§ 3486. Authorized investigative demand procedures

7 “(a) AUTHORIZATION.—(1) In any investigation re-
8 lating to functions set forth in paragraph (2), the Attorney
9 General or the Attorney General’s designee may issue in
10 writing and cause to be served a summons compelling the
11 attendance and testimony of witnesses and requiring the
12 production of any records (including any books, papers,
13 documents, electronic media, or other objects or tangible
14 things), which may be relevant to an authorized law en-
15 forcement inquiry, that a person or legal entity may pos-
16 sess or have care, custody, or control. The attendance of
17 witnesses and the production of records may be required
18 from any place in any State or in any territory or other
19 place subject to the jurisdiction of the United States at
20 any designated place of hearing; except that a witness
21 shall not be required to appear at any hearing more than
22 500 miles distant from the place where he was served with
23 a subpoena. Witnesses summoned under this section shall
24 be paid the same fees and mileage that are paid witnesses
25 in the courts of the United States. A summons requiring
26 the production of records shall describe the objects re-

1 quired to be produced and prescribe a return date within
2 a reasonable period of time within which the objects can
3 be assembled and made available.

4 “(2) Investigative demands utilizing an administra-
5 tive summons are authorized for:

6 “(A) Any investigation with respect to any act
7 or activity constituting an offense involving a Fed-
8 eral health care offense as that term is defined in
9 section 24 of title 18, United States Code.

10 “(B) Any investigation, with respect to viola-
11 tions of sections 1073 and 1074 of title 18, United
12 States Code, or in which an individual has been law-
13 fully charged with a Federal offense and such indi-
14 vidual is avoiding prosecution or custody or confine-
15 ment after conviction of such offense or attempt.

16 “(b) SERVICE.—A subpoena issued under this section
17 may be served by any person designated in the subpoena
18 to serve it. Service upon a natural person may be made
19 by personal delivery of the subpoena to him. Service may
20 be made upon a domestic or foreign corporation or upon
21 a partnership or other unincorporated association which
22 is subject to suit under a common name, by delivering the
23 subpoena to an officer, to a managing or general agent,
24 or to any other agent authorized by appointment or by
25 law to receive service of process. The affidavit of the per-

1 son serving the subpoena entered on a true copy thereof
2 by the person serving it shall be proof of service.

3 “(c) ENFORCEMENT.—In the case of contumacy by
4 or refusal to obey a subpoena issued to any person, the
5 Attorney General may invoke the aid of any court of the
6 United States within the jurisdiction of which the inves-
7 tigation is carried on or of which the subpoenaed person
8 is an inhabitant, or in which he carries on business or may
9 be found, to compel compliance with the subpoena. The
10 court may issue an order requiring the subpoenaed person
11 to appear before the Attorney General to produce records,
12 if so ordered, or to give testimony touching the matter
13 under investigation. Any failure to obey the order of the
14 court may be punished by the court as a contempt thereof.
15 All process in any such case may be served in any judicial
16 district in which such person may be found.

17 “(d) IMMUNITY FROM CIVIL LIABILITY.—Notwith-
18 standing any Federal, State, or local law, any person, in-
19 cluding officers, agents, and employees, receiving a sum-
20 mons under this section, who complies in good faith with
21 the summons and thus produces the materials sought,
22 shall not be liable in any court of any State or the United
23 States to any customer or other person for such produc-
24 tion or for nondisclosure of that production to the cus-
25 tomer.”.

1 (b) CLERICAL AMENDMENT.—The table of sections
2 at the beginning of chapter 223 of title 18, United States
3 Code, is amended by inserting after the item relating to
4 section 3485 the following new item:

“3486. Authorized investigative demand procedures.”.

5 (c) CONFORMING AMENDMENT.—Section
6 1510(b)(3)(B) of title 18, United States Code, is amended
7 by inserting “or a Federal Bureau of Investigation sum-
8 mons (issued under section 3486 of title 18),” after “sub-
9 poena”.

10 **SEC. 211. GRAND JURY DISCLOSURE.**

11 Section 3322 of title 18, United States Code, is
12 amended—

13 (1) by redesignating subsections (c) and (d) as
14 subsections (d) and (e), respectively; and

15 (2) by inserting after subsection (b) the follow-
16 ing:

17 “(c) A person who is privy to grand jury information
18 concerning a health care offense—

19 “(1) received in the course of duty as an attor-
20 ney for the Government; or

21 “(2) disclosed under rule 6(e)(3)(A)(ii) of the
22 Federal Rules of Criminal Procedure;

23 may disclose that information to an attorney for the Gov-
24 ernment to use in any civil investigation or proceeding re-

1 lated to a Federal health care offense (as defined in sec-
2 tion 24 of this title).”.

3 **SEC. 212. MISCELLANEOUS AMENDMENTS TO TITLE 18,**
4 **UNITED STATES CODE.**

5 (a) LAUNDERING OF MONETARY INSTRUMENTS.—
6 Section 1956(c)(7) of title 18, United States Code, is
7 amended by adding at the end thereof the following:

8 “(F) Any act or activity constituting an offense
9 involving a Federal health care offense as that term
10 is defined in section 24 of title 18, United States
11 Code.”.

12 (b) ENHANCED PENALTIES.—Section 2326(2) of title
13 18, United States Code, is amended by striking “sections
14 that—” and inserting “or in the case of a Federal health
15 care offense as that term is defined in section 24 of this
16 title, that—”.

17 (c) AUTHORIZATION FOR INTERCEPTION OF WIRE,
18 ORAL, OR ELECTRONIC COMMUNICATIONS.—Section
19 2516(1)(c) of title 18, United States Code, is amended—

20 (1) by inserting “section 226 (bribery and graft
21 in connection with health care), section 227 (illegal
22 remunerations)” after “section 224 (bribery in
23 sporting contests),”; and

1 (2) by inserting "section 1347 (health care
2 fraud)" after "section 1344 (relating to bank
3 fraud),".

4 (d) DEFINITIONS.—Section 1961(1) of title 18,
5 United States Code, is amended—

6 (1) by inserting "sections 226 and 227 (relating
7 to bribery and graft, and illegal remuneration in
8 connection with health care)" after "section 224 (re-
9 lating to sports bribery),";

10 (2) by inserting "section 669 (relating to theft
11 or embezzlement in connection with health care)"
12 after "section 664 (relating to embezzlement from
13 pension and welfare funds),"; and

14 (3) by inserting "section 1347 (relating to
15 health care fraud)" after "section 1344 (relating to
16 financial institution fraud),".

17 (e) CRIMINAL FORFEITURE.—Section 982(a) of title
18 18, United States Code, is amended by adding at the end
19 the following new paragraph:

20 “(6) The court in imposing sentence on a per-
21 son convicted of a Federal health care offense as de-
22 fined in section 24 of this title, shall order that the
23 offender forfeit to the United States any real or per-
24 sonal property constituting or derived from proceeds

that the offender obtained directly or indirectly as the result of the offense.”.

(f) REWARDS FOR INFORMATION LEADING TO PROSECUTION AND CONVICTION.—Section 3059(c)(1) of title 18, United States Code, is amended by inserting “or furnishes information unknown to the Government relating to a possible prosecution of a Federal health care offense as defined in section 24 of this title, which results in a conviction” before the period at the end.

TITLE III—ANTI-FRAUD INITIATIVES UNDER MEDICARE AND MEDICAID

SEC. 301. REVISION TO CURRENT PENALTIES.

(a) PERMISSIVE EXCLUSION OF INDIVIDUALS WITH OWNERSHIP OR CONTROL INTEREST IN SANCTIONED ENTITIES.—Section 1128(b) of the Social Security Act (42 U.S.C. 1320a-7(b)) is amended by adding at the end the following new paragraph:

“(15) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—Any individual who has a direct or indirect ownership or control interest of 5 percent or more, or an ownership or control interest (as defined in section 1124(a)(3)) in, or who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of, an entity—

1 “(A) that has been convicted of any of-
2 fense described in subsection (a) or in para-
3 graph (1), (2), or (3) of this subsection;

4 “(B) against which a civil monetary pen-
5 alty has been assessed under section 1128A; or

6 “(C) that has been excluded from partici-
7 pation under a program under title XVIII or
8 under a State health care program.”.

9 (b) IMPOSITION OF CIVIL MONETARY PENALTY ON
10 EMPLOYER BILLING FOR SERVICES FURNISHED BY EX-
11 CLUDED EMPLOYEE.—Section 1128A(a)(1) of the Social
12 Security Act (42 U.S.C. 1320a-7a(a)(1)) is amended—

13 (1) by striking “or” at the end of subparagraph
14 (C);

15 (2) by striking “; or” at the end of subpara-
16 graph (D) and inserting “, or”; and

17 (3) by adding at the end the following new sub-
18 paragraph:

19 “(E) is for a medical or other item or serv-
20 ice furnished by an individual who is an em-
21 ployee or agent of the person during a period
22 in which such employee or agent was excluded
23 from the program under which the claim was
24 made on any of the grounds for exclusion de-
25 scribed in subparagraph (D);”.

1 (c) DEPOSIT OF PENALTIES INTO HEALTH CARE
 2 FRAUD AND ABUSE CONTROL ACCOUNT.—Section
 3 1128A(f)(3) of such Act (42 U.S.C. 1320a–7a(f)(3)) is
 4 amended by striking “as miscellaneous receipts of the
 5 Treasury of the United States” and inserting “in the
 6 Health Care Fraud and Abuse Control Account estab-
 7 lished under section 104 of the Health Care Fraud and
 8 Abuse Prevention Act of 1996”.

9 (d) EFFECTIVE DATE.—The amendments made by
 10 this section shall apply with respect to sanctions imposed
 11 for acts or omissions occurring on or after the date of the
 12 enactment of this Act.

13 **SEC. 302. SOLICITATION AND PUBLICATION OF MODIFICA-**
 14 **TIONS TO EXISTING SAFE HARBORS AND NEW**
 15 **SAFE HARBORS; ADDITIONAL EXCEPTION**
 16 **FOR CERTAIN DISCOUNTING AND MANAGED**
 17 **CARE ARRANGEMENTS.**

18 (a) IN GENERAL.—

19 (1) SOLICITATION OF PROPOSALS FOR SAFE
 20 HARBORS.—Not later than one year after the date
 21 of the enactment of this Act and not less than every
 22 2 years thereafter, the Secretary of Health and
 23 Human Services (hereafter in this title referred to as
 24 the “Secretary”) shall publish a notice in the Fed-

1 eral Register soliciting proposals, which will be ac-
2 cepted during a 60-day period, for—

3 (A) modifications to existing safe harbors
4 issued pursuant to section 14(a) of the Medi-
5 care and Medicaid Patient and Program Protec-
6 tion Act of 1987; and

7 (B) additional safe harbors specifying pay-
8 ment practices that shall not be treated as a
9 criminal offense under section 1128B(b) of the
10 Social Security Act and shall not serve as the
11 basis for an exclusion under section 1128(b)(7)
12 of such Act.

13 (2) PUBLICATION OF PROPOSED MODIFICA-
14 TIONS AND PROPOSED ADDITIONAL SAFE HAR-
15 BORS.—After considering the proposals described in
16 paragraph (1), the Secretary, in consultation with
17 the Attorney General, shall publish in the Federal
18 Register proposed modifications to existing safe har-
19 bors and proposed additional safe harbors, if appro-
20 priate, with a 60-day comment period. After consid-
21 ering any public comments received during this pe-
22 riod, the Secretary shall issue final rules modifying
23 the existing safe harbors and establishing new safe
24 harbors, as appropriate.

(3) REPORT.—The Inspector General of the Department of Health and Human Services (hereafter in this section referred to as the “Inspector General”) shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978, describe the proposals received under paragraph (1) and explain which proposals were included in the publication described in paragraph (2), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

(b) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under subsection (a)(2), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

(1) An increase or decrease in access to health care services.

(2) An increase or decrease in the quality of health care services.

(3) An increase or decrease in patient freedom of choice among health care providers.

(4) An increase or decrease in competition among health care providers.

1 (5) An increase or decrease in the ability of
2 health care facilities to provide services in medically
3 underserved areas or to medically underserved popu-
4 lations.

5 (6) An increase or decrease in the cost to health
6 care programs operated or financed by the Federal,
7 State, or local governments.

8 (7) An increase or decrease in the potential
9 overutilization of health care services.

10 (8) The existence or nonexistence of any poten-
11 tial financial benefit to a health care professional or
12 provider which may vary based on their decisions
13 of—

14 (A) whether to order a health care item or
15 service; or

16 (B) whether to arrange for a referral of
17 health care items or services to a particular
18 practitioner or provider.

19 (9) Any other factors the Secretary deems ap-
20 propriate in the interest of preventing fraud and
21 abuse in health care programs operated or financed
22 by the Federal, State, or local governments.

23 (c) EXCEPTION TO ANTI-KICKBACK PROHIBITIONS
24 FOR CERTAIN DISCOUNTING AND MANAGED CARE AR-
25 RANGEMENTS.—

(1) IN GENERAL.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a-7b(b)(3)) is amended—

(A) by striking “and” at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide, whether through a withhold, capitation, incentive pool, per diem payment, or any other similar risk arrangement which places the individual or entity at substantial financial risk.”.

1 (2) EFFECTIVE DATE.—The amendments made
 2 by this subsection shall apply to written agreements
 3 entered into on or after January 1, 1997.

4 **SEC. 303. EXPEDITING IMPLEMENTATION OF PAYMENT AD-**
 5 **JUSTMENTS FOR DURABLE MEDICAL EQUIP-**
 6 **MENT BASED UPON INHERENT REASONABLE-**
 7 **NESS.**

8 The first sentence of section 1834(a)(10)(B) of the
 9 Social Security Act (42 U.S.C. 1395m(a)(10)(B)) is
 10 amended by striking the period and inserting the follow-
 11 ing: “, except that (notwithstanding any provision of such
 12 paragraphs or this title) the Secretary shall make an ad-
 13 justment in payment for an item under this subsection
 14 pursuant to this subparagraph through the issuance of an
 15 interim final regulation issued not later than 1 year after
 16 the Secretary initially proposes to make the adjustment.”.

17 **SEC. 304. REQUIRING ANNUAL NOTICE TO MEDICARE**
 18 **BENEFICIARIES OF NEED TO PREVENT**
 19 **FRAUD AND ABUSE AGAINST MEDICARE PRO-**
 20 **GRAM.**

21 (a) IN GENERAL.—Section 1804(a) of the Social Se-
 22 curity Act (42 U.S.C. 1395b-2(a)) is amended—

23 (1) by striking “and” at the end of paragraph
 24 (2);

1 (2) by striking the period at the end of para-
2 graph (3) and inserting “, and”; and

3 (3) by inserting after paragraph (3) the follow-
4 ing new paragraph:

5 “(4) a description of the costs to the medicare
6 program of waste, fraud, and abuse, together with
7 suggestions for steps which medicare beneficiaries
8 may take to help combat waste, fraud, and abuse
9 against the program, including the toll-free tele-
10 phone number operated by the Secretary and the In-
11 spector General of the Department of Health and
12 Human Services for reporting information on fraud
13 and abuse against the program and the potential
14 availability of a reward for individuals reporting in-
15 formation which leads to a criminal prosecution and
16 conviction for health care fraud under title 18, Unit-
17 ed States Code.”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall apply to the annual notice mailed
20 under section 1804(a) of the Social Security Act for years
21 beginning with 1997.

1 **SEC. 305. REQUIRING USE OF SINGLE PROVIDER NUMBER**
2 **IN SUBMISSION OF CLAIMS FOR PAYMENT**
3 **UNDER MEDICARE AND MEDICAID.**

4 (a) USE OF SINGLE NUMBER UNDER MEDICARE; IN-
5 CLUDING DOCUMENTATION ON SOLVENCY AND FISCAL
6 INTEGRITY.—Section 1842(r) of the Social Security Act
7 (42 U.S.C. 1395u(r)) is amended to read as follows:

8 “(r)(1) Not later than 1 year after the date of the
9 enactment of the Health Care Fraud and Abuse Preven-
10 tion Act of 1996, the Secretary shall establish a system
11 which provides for a unique identifier for each individual
12 or entity who furnishes items or services for which pay-
13 ment may be made under this part.

14 “(2) The Secretary may not provide a unique identi-
15 fier to an individual or entity under the system established
16 under paragraph (1) unless the individual or entity sub-
17 mits such documentation relating to financial solvency and
18 fiscal integrity as the Secretary may require to ensure that
19 the issuance of the unique identifier to the individual or
20 entity will not expose the program under this part to
21 waste, fraud, and abuse, except that the Secretary may
22 waive the application of this paragraph in the case of—

23 “(A) a provider of services (as defined in sec-
24 tion 1861(u)); or

25 “(B) an individual or entity eligible to receive
26 payment for items or services furnished under this

1 part on the basis of licensure or authorization under
2 State law (or the State regulatory mechanism pro-
3 vided by State law) to furnish the items or services.

4 “(3) No payment may be made under this title for
5 any item or service furnished by an individual or entity
6 unless the claim for payment with respect to the item or
7 service includes the unique identifier provided to the indi-
8 vidual or entity under the system established under para-
9 graph (1).”.

10 (b) PROVIDING MEDICARE NUMBER FOR SUBMIS-
11 SION OF MEDICAID CLAIMS.—Section 1902(x) of such Act
12 (42 U.S.C. 1396a(x)) is amended—

13 (1) by striking “(x)” and inserting “(x)(1)”;
14 and

15 (2) by adding at the end the following new
16 paragraph:

17 “(2) If an individual or entity submitting a claim to
18 the State for payment for providing medical assistance
19 under the State plan has a unique identifier assigned by
20 the Secretary pursuant to section 1842(r) for purposes of
21 title XVIII, the individual or entity shall include the iden-
22 tifier with such claim.”.

1 SEC. 306. LIABILITY OF CARRIERS AND FISCAL
2 INTERMEDIARIES FOR CLAIMS SUBMITTED
3 BY EXCLUDED PROVIDERS.

4 (a) REIMBURSEMENT TO SECRETARY FOR AMOUNTS
5 PAID TO EXCLUDED PROVIDERS.—

6 (1) REQUIREMENT FOR FISCAL
7 INTERMEDIARIES.—

8 (A) IN GENERAL.—Section 1816 of the So-
9 cial Security Act (42 U.S.C. 1395h) is amended
10 by adding at the end the following new sub-
11 section:

12 “(l) An agreement with an agency or organization
13 under this section shall require that such agency or orga-
14 nization reimburse the Secretary for any amounts paid for
15 a service under this title which is furnished by an individ-
16 ual or entity during any period for which the individual
17 or entity is excluded pursuant to section 1128, 1128A,
18 1156, or subsection (j)(2) from participation in the pro-
19 gram under this title, if the amounts are paid after the
20 Secretary notifies the agency or organization of the exclu-
21 sion.”.

22 (B) CONFORMING AMENDMENT.—Section
23 1816(i) of such Act (42 U.S.C. 1395h(i)) is
24 amended by adding at the end the following
25 new paragraph:

1 “(4) Nothing in this subsection shall be construed to
2 prohibit reimbursement by an agency or organization
3 under subsection (l).”.

4 (2) REQUIREMENT FOR CARRIERS.—Section
5 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)) is
6 amended—

7 (A) by striking “and” at the end of sub-
8 paragraph (I); and

9 (B) by inserting after subparagraph (I) the
10 following new subparagraph:

11 “(J) will reimburse the Secretary for any
12 amounts paid for an item or service under this part
13 which is furnished by an individual or entity during
14 any period for which the individual or entity is ex-
15 cluded pursuant to section 1128, 1128A, 1156, or
16 subsection (j)(2) from participation in the program
17 under this title, if the amounts are paid after the
18 Secretary notifies the carrier of the exclusion; and”.

19 (b) CONFORMING REPEAL OF MANDATORY PAYMENT
20 RULE.—Section 1862(e)(2) of such Act (42 U.S.C.
21 1395y(e)(2)) is amended to read as follows:

22 “(2) No individual or entity may bill (or collect any
23 amount from) any individual for any item or service for
24 which payment is denied under paragraph (1). No person
25 is liable for payment of any amounts billed for such an

1 item or service in violation of the previous sentence. If an
 2 individual or entity knowingly and willfully bills (or col-
 3 lects an amount) for such an item or service in violation
 4 of such sentence, the Secretary may apply sanctions
 5 against the individual or entity in the same manner as
 6 the Secretary may apply sanctions against a physician in
 7 accordance with subsection (j)(2) in the same manner as
 8 such section applies with respect to a physician. Para-
 9 graph (4) of subsection (j) shall apply in this paragraph
 10 in the same manner as such paragraph applies to such
 11 section.”.

12 **SEC. 307. REQUIRING FISCAL INTERMEDIARIES AND CAR-**
 13 **RIERS TO USE AUTOMATED DATA PROCESS-**
 14 **ING EQUIPMENT COMPARABLE TO EQUIP-**
 15 **MENT USED IN PRIVATE INSURANCE BUSI-**
 16 **NESS.**

17 (a) IN GENERAL.—

18 (1) REQUIREMENT FOR FISCAL
 19 INTERMEDIARIES.—Section 1816(f)(2) of the Social
 20 Security Act (42 U.S.C. 1395h(f)(2)) is amended—

21 (A) by striking “and” at the end of sub-
 22 paragraph (A);

23 (B) by striking the period at the end of
 24 subparagraph (B) and inserting “; and”; and

1 (C) by adding at the end the following new
2 subparagraph:

3 “(C) in the case of an agency or organization
4 which processes claims for private insurance, a re-
5 quirement that the automated data processing equip-
6 ment used by the agency or organization in carrying
7 out the agreement under this section is as effective
8 (or more effective) in detecting code manipulations,
9 unbundling, global service violations, double billings,
10 and other forms of waste, fraud, and abuse as the
11 equipment the agency or organization uses in proc-
12 essing claims for private insurance.”.

13 (2) REQUIREMENT FOR CARRIERS.—Section
14 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)) is
15 amended—

16 (A) by striking “and” at the end of sub-
17 paragraph (I); and

18 (B) by inserting after subparagraph (I) the
19 following new subparagraph:

20 “(J) if it processes claims for private insurance,
21 will use automated data processing equipment in
22 carrying out the contract that is as effective (or
23 more effective) in detecting code manipulations,
24 unbundling, global service violations, double billings,
25 and other forms of waste, fraud, and abuse as the

1 equipment it uses in processing claims for private in-
2 surance; and”.

3 (b) **EFFECTIVE DATE.**—The amendments made by
4 subsection (a) shall apply with respect to agreements with
5 agencies and organizations under section 1816 of the So-
6 cial Security Act and contracts with carriers under section
7 1842 of such Act for contract years beginning after the
8 date of the enactment of this Act.

9 **SEC. 308. NONDISCHARGEABILITY UNDER BANKRUPTCY**

10 **CODE OF AMOUNTS OWED FOR OVERPAY-**
11 **MENTS.**

12 (a) **IN GENERAL.**—Section 523(a) of title 11, United
13 States Code, is amended—

14 (1) by striking the period at the end of para-
15 graph (16) and inserting “; or”; and

16 (2) by adding at the end the following new
17 paragraph:

18 “(17) to the extent such debt is for amounts
19 owed for overpayments made under title XVIII of
20 the Social Security Act.”.

21 (b) **APPLICABILITY UNDER CHAPTER 13.**—Section
22 1328(a)(2) of title 11, United States Code, is amended
23 by striking “or (9)” and inserting “(9), or (17)”.

24 (c) **EFFECTIVE DATE.**—The amendments made by
25 this section shall apply only with respect to cases com-

1 menced under title 11, United States Code, after the date
2 of the enactment of this Act.

104TH CONGRESS
1ST SESSION

H. R. 1850

To improve Federal enforcement against health care fraud and abuse.

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 1995

Mr. TOWNS introduced the following bill; which was referred to the Committee on Government Reform and Oversight

A BILL

To improve Federal enforcement against health care fraud and abuse.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Health Fraud and
5 Abuse Act of 1995".

6 **SEC. 2. HEALTH CARE FRAUD AND ABUSE.**

7 (a) FEDERAL ENFORCEMENT BY INSPECTORS GEN-
8 ERAL.—

9 (1) AUDITS, INVESTIGATIONS, INSPECTIONS,
10 AND EVALUATIONS.—The Inspector General of each
11 of the Department of Health and Human Services,

1 the Department of Defense, the Department of
2 Labor, the Office of Personnel Management, and the
3 Department of Veterans Affairs shall conduct au-
4 dits, civil and criminal investigations, inspections,
5 and evaluations relating to the prevention, detection,
6 and control of health care fraud and abuse in viola-
7 tion of any Federal law.

8 (2) POWERS.—For purposes of carrying out du-
9 ties and responsibilities under paragraph (1), each
10 Inspector General referred to in paragraph (1) may
11 exercise powers that are available to the Inspector
12 General for purposes of audits, investigations, and
13 other activities under the Inspector General Act of
14 1978 (5 U.S.C. App.).

15 (3) COORDINATION AND REVIEW OF ACTIVITIES
16 OF OTHER FEDERAL, STATE, AND LOCAL AGEN-
17 CIES.—

18 (A) PROGRAM.—The Inspector General
19 shall—

20 (i) jointly establish, on the effective
21 date specified in subsection (j)(1), a pro-
22 gram to prevent, detect, and control health
23 care fraud and abuse in violation of any
24 Federal law, which considers the activities
25 of Federal, State, and local law enforce-

1 ment agencies, Federal and State agencies
2 responsible for the licensing and certifi-
3 cation of health care providers, and State
4 agencies designated under subsection
5 (b)(1)(A); and

6 (ii) publish a description of the pro-
7 gram in the Federal Register, by not later
8 than June 30, 1996.

9 (B) ANNUAL INVESTIGATIVE PLAN.—Each
10 Inspector General referred to in paragraph (1)
11 shall develop an annual investigative plan for
12 the prevention, detection, and control of health
13 care fraud and abuse in accordance with the
14 program established under subparagraph (A).

15 (4) CONSULTATIONS.—Each of the Inspectors
16 General referred to in paragraph (1) shall regularly
17 consult with each other, with Federal, State, and
18 local law enforcement agencies, with Federal and
19 State agencies responsible for the licensing and cer-
20 tification of health care providers, and with Health
21 Care Fraud and Abuse Control Units, in order to
22 assist in coordinating the prevention, detection, and
23 control of health care fraud and abuse in violation
24 of any Federal law.

25 (b) STATE ENFORCEMENT.—

(1) DESIGNATION OF STATE AGENCIES AND ESTABLISHMENT OF HEALTH CARE FRAUD AND ABUSE CONTROL UNIT.—The Governor of each State—

(A) shall, consistent with State law, designate agencies of the State which conduct, supervise, and coordinate audits, civil and criminal investigations, inspections, and evaluations relating to the prevention, detection, and control of health care fraud and abuse in violation of any Federal law in the State; and

(B) may establish and maintain in accordance with paragraph (2) a State agency to act as a Health Care Fraud and Abuse Control Unit for purposes of this section.

(2) HEALTH CARE FRAUD AND ABUSE CONTROL UNIT REQUIREMENTS.—A Health Care Fraud and Abuse Control Unit established by a State under paragraph (1)(B) shall be a single identifiable entity of State government which is separate and distinct from any State agency with principal responsibility for the administration of health care programs, and which meets the following requirements:

(A) The entity—

(i) is a unit of the office of the State Attorney General or of another department

1 of State government that possesses state-
2 wide authority to prosecute individuals for
3 criminal violations;

4 (ii) is in a State the constitution of
5 which does not provide for the criminal
6 prosecution of individuals by a statewide
7 authority, and has formal procedures, ap-
8 proved by the Secretary, that assure it will
9 refer suspected criminal violations relating
10 to health care fraud or abuse in violation
11 of any Federal law to the appropriate au-
12 thority or authorities of the State for pros-
13 ecution and assure it will assist such au-
14 thority or authorities in such prosecutions;
15 or

16 (iii) has a formal working relationship
17 with the office of the State Attorney Gen-
18 eral or the appropriate authority or au-
19 thorities for prosecution and has formal
20 procedures (including procedures under
21 which it will refer suspected criminal viola-
22 tions to such office), that provide effective
23 coordination of activities between the
24 Health Care Fraud and Abuse Control
25 Unit and such office with respect to the

6

1 detection, investigation, and prosecution of
2 suspected health care fraud or abuse in
3 violation of any Federal law.

4 (B) The entity conducts a statewide pro-
5 gram for the investigation and prosecution of
6 violations of all applicable State laws regarding
7 any and all aspects of health care fraud and
8 abuse in violation of any Federal law.

9 (C) The entity has procedures for—

10 (i) reviewing complaints of the abuse
11 or neglect of patients of health care facili-
12 ties in the State; and

13 (ii) where appropriate, investigating
14 and prosecuting such complaints under the
15 criminal laws of the State or for referring
16 the complaints to other State or Federal
17 agencies for action.

18 (D) The entity provides for the collection,
19 or referral for collection to the appropriate
20 agency, of overpayments that—

21 (i) are made under any federally fund-
22 ed or mandated health care program re-
23 quired by this Act; and

24 (ii) it discovers in carrying out its ac-
25 tivities.

1 (E) The entity employs attorneys, auditors,
2 investigators, and other necessary personnel, is
3 organized in such a manner, and provides suffi-
4 cient resources, as is necessary to promote the
5 effective and efficient conduct of its activities.

6 (3) SUBMISSION OF ANNUAL PLAN.—Each
7 Health Care Fraud and Abuse Control Unit may
8 submit each year to the Inspector General a plan for
9 preventing, detecting, and controlling, consistent
10 with the program established under subsection
11 (a)(3)(A), health care fraud and abuse in violation
12 of any Federal law.

13 (4) APPROVAL OF ANNUAL PLAN.—The Inspec-
14 tor General shall approve a plan submitted under
15 paragraph (3) by the Health Care Fraud and Abuse
16 Control Unit of a State, unless the Inspector Gen-
17 eral establishes that the plan—

18 (A) is inconsistent with the program estab-
19 lished under subsection (a)(3)(A); or

20 (B) will not enable the agencies of the
21 State designated under paragraph (1)(A) to
22 prevent, detect, and control health care fraud
23 and abuse in violation of any Federal law.

24 (5) REPORTS.—Each Health Care Fraud and
25 Abuse Control Unit shall submit to the Inspector

1 General an annual report containing such informa-
2 tion as the Inspector General determines to be nec-
3 essary.

4 (6) SEMIANNUAL REPORTS OF INSPECTOR GEN-
5 ERAL OF HEALTH AND HUMAN SERVICES.—The In-
6 spector General shall include in each semiannual re-
7 port of the Inspector General to the Congress under
8 section 5(a) of the Inspector General Act of 1978 (5
9 U.S.C. App.) an assessment of the Inspector General
10 of how well States are preventing, detecting, and
11 controlling health care fraud and abuse.

12 (c) PAYMENTS TO STATES.—

13 (1) IN GENERAL.—For each year for which a
14 State has a plan approved under subsection (b)(4),
15 and subject to the availability of appropriations, the
16 Inspector General shall pay to the State for each
17 quarter an amount equal to 75 percent of the sums
18 expended during the quarter by agencies designated
19 by the Governor of the State under subsection
20 (b)(1)(A) in conducting activities described in that
21 subsection.

22 (2) TIME OF PAYMENT.—The Inspector General
23 shall make a payment under paragraph (1) for a
24 quarter by not later than 30 days after the end of
25 the quarter.

1 (3) PAYMENTS ARE ADDITIONAL.—Payments to
2 a State under this subsection shall be in addition to
3 any amounts paid under subsection (g).

4 (d) DATA SHARING.—The Inspector General shall es-
5 tablish a program for the sharing among Federal agencies,
6 State and local law enforcement agencies, and health care
7 providers and insurers, consistent with data sharing provi-
8 sions of subtitle B, of data related to possible health care
9 fraud and abuse in violation of any Federal law.

10 (e) HEALTH CARE FRAUD AND ABUSE CONTROL AC-
11 COUNT.—

12 (1) ESTABLISHMENT.—There is established on
13 the books of the Treasury of the United States a
14 separate account, which shall be known as the
15 Health Care Fraud and Abuse Control Account. The
16 Account shall consist of—

17 (A) the Health Care Fraud and Abuse Ex-
18 penses Subaccount; and

19 (B) the Health Care Fraud and Abuse Re-
20 serve Subaccount.

21 (2) EXPENSES SUBACCOUNT.—

22 (A) CONTENTS.—The Expenses Sub-
23 account consists of—

24 (i) amounts deposited under subpara-
25 graph (B); and

1 (ii) amounts transferred from the Re-
2 serve Subaccount and deposited under
3 paragraph (3)(B).

4 (B) DEPOSITS.—Except as provided in
5 paragraph (3)(A), there shall be deposited in
6 the Expenses Subaccount all amounts received
7 by the United States as—

8 (i) fines for health care fraud and
9 abuse in violation of any Federal law;

10 (ii) civil penalties or damages (other
11 than restitution) in actions under section
12 3729 or 3730 of title 31, United States
13 Code (commonly referred to as the “False
14 Claims Act”), that are based on health
15 care fraud and abuse in violation of any
16 Federal law;

17 (iii) administrative penalties under the
18 Social Security Act;

19 (iv) proceeds of seizures and forfeit-
20 ures of property for acts or omissions that
21 constitute health care fraud or abuse in
22 violation of any Federal law; and

23 (v) money and proceeds of property
24 that are accepted under subsection (f).

1 (C) USE.—Amounts in the Expenses Sub-
2 account shall be available to the Inspector Gen-
3 eral, under such terms and conditions as the
4 Inspector General determines to be appropriate,
5 for—

6 (i) paying expenses incurred by their
7 respective agencies in carrying out activi-
8 ties under subsection (a); and

9 (ii) making reimbursements to other
10 Inspectors General and Federal, State, and
11 local agencies in accordance with sub-
12 section (g).

13 (3) RESERVE SUBACCOUNT.—

14 (A) DEPOSITS.—An amount otherwise re-
15 quired under paragraph (2)(A) to be deposited
16 in the Expenses Subaccount in a fiscal year
17 shall be deposited in the Reserve Subaccount,
18 if—

19 (i) the amount in the Expenses Sub-
20 account is greater than \$500,000,000; and

21 (ii) the deposit of that amount in the
22 Expenses Subaccount would result in the
23 amount in the Expenses Subaccount ex-
24 ceeding 110 percent of the total amount

deposited in the Expenses Subaccount in the preceding fiscal year.

(B) TRANSFERS TO EXPENSES SUBACCOUNT.—

(i) ESTIMATION OF SHORTFALL.—Not later than the first day of the last quarter of each fiscal year, the Inspector General shall estimate whether sufficient amounts will be available during such quarter in the Expenses Subaccount for the uses described in paragraph (2)(C).

(ii) TRANSFER TO COVER SHORTFALL.—If the Inspector General estimates under clause (i) that there will not be available sufficient amounts in the Expenses Subaccount during the last quarter of a fiscal year, there shall be transferred from the Reserve Subaccount and deposited in the Expenses Subaccount such amount as the Inspector General estimates is required to ensure that sufficient amounts are available in the Expenses Subaccount during such quarter.

(C) LIMITATION ON AMOUNT CARRIED OVER TO SUCCEEDING FISCAL YEAR.—There

1 shall be transferred to the general fund of the
2 Treasury any amount remaining in the Reserve
3 Subaccount at the end of a fiscal year (after
4 any transfer made under subparagraph (B)) in
5 excess of 10 percent of the total amount au-
6 thorized to be deposited in the Expenses Sub-
7 account (consistent with subparagraph (A))
8 during the fiscal year.

9 (f) ACCEPTANCE OF GIFTS, BEQUESTS, AND DE-
10 VISES.—Any Inspector General referred to in subsection
11 (a)(1) may accept, use, and dispose of gifts, bequests, or
12 devises of services or property (real or personal), for the
13 purpose of aiding or facilitating activities under this sec-
14 tion regarding health care fraud and abuse. Gifts, be-
15 quests, or devises of money and proceeds from sales of
16 other property received as gifts, bequests, or devises shall
17 be deposited in the Account and shall be available for use
18 in accordance with subsection (e)(2)(C).

19 (g) REIMBURSEMENTS OF EXPENSES AND OTHER
20 PAYMENTS TO PARTICIPATING AGENCIES.—

21 (1) REIMBURSEMENT OF EXPENSES OF FED-
22 ERAL AGENCIES.—The Inspector General, subject to
23 the availability of amounts in the Account, shall
24 promptly reimburse Federal agencies for expenses
25 incurred in carrying out subsection (a).

1 (2) PAYMENTS TO STATE AND LOCAL LAW EN-
2 FORCEMENT AGENCIES.—The Inspector General,
3 subject to the availability of amounts in the Account,
4 shall promptly pay to any State or local law enforce-
5 ment agency that participated directly in any activ-
6 ity which led to deposits in the Account, or property
7 the proceeds of which are deposited in the Account,
8 an amount that reflects generally and equitably the
9 participation of the agency in the activity.

10 (3) FUNDS USED TO SUPPLEMENT AGENCY AP-
11 PROPRIATIONS.—It is intended that disbursements
12 made from the Account to any Federal agency be
13 used to increase and not supplant the recipient
14 agency's appropriated operating budget.

15 (h) ACCOUNT PAYMENTS ADVISORY BOARD.—

16 (1) ESTABLISHMENT.—There is established the
17 Account Payments Advisory Board, which shall
18 make recommendations to the Inspector General re-
19 garding the equitable allocation of payments from
20 the Account.

21 (2) MEMBERSHIP.—The Board shall consist
22 of—

23 (A) each of the Inspectors General referred
24 to in subsection (a)(1), other than the Inspector

1 General of the Department of Health and
2 Human Services; and

3 (B) 10 members appointed by the Inspec-
4 tor General of the Department of Health and
5 Human Services to represent Health Care
6 Fraud and Abuse Control Units, of whom one
7 shall be appointed—

8 (i) for each of the 10 regions estab-
9 lished by the Director of the Office of
10 Management and Budget under Office of
11 Management and Budget Circular A-105,
12 to represent Units in that region; and

13 (ii) from among individuals rec-
14 ommended by the heads of those agencies
15 in that region.

16 (3) TERMS.—The term of a member of the
17 Board appointed under paragraph (2)(B) shall be 3
18 years, except that of such members first appointed
19 3 members shall serve an initial term of one year
20 and 3 members shall serve an initial term of 2 years,
21 as specified by the Inspector General at the time of
22 appointment.

23 (4) VACANCIES.—A vacancy on the Board shall
24 be filled in the same manner in which the original
25 appointment was made, except that an individual ap-

1 pointed to fill a vacancy occurring before the expira-
2 tion of the term for which the individual is ap-
3 pointed shall be appointed only for the remainder of
4 that term.

5 (5) CHAIRPERSON AND BYLAWS.—The Board
6 shall elect one of its members as chairperson and
7 shall adopt bylaws.

8 (6) COMPENSATION AND EXPENSES.—Members
9 of the Board shall serve without compensation, ex-
10 cept that the Inspector General may pay the ex-
11 penses reasonably incurred by the Board in carrying
12 out its functions under this section.

13 (7) NO TERMINATION.—Section 14(a)(2) of the
14 Federal Advisory Committee Act (5 U.S.C. App.)
15 does not apply to the Board.

16 (i) DEFINITIONS.—In this section:

17 (1) ACCOUNT.—The term “Account” means the
18 Health Care Fraud and Abuse Control Account es-
19 tablished by subsection (e)(1).

20 (2) EXPENSES SUBACCOUNT.—The term “Ex-
21 penses Subaccount” means the Health Care Fraud
22 and Abuse Expenses Subaccount of the Account.

23 (3) HEALTH CARE FRAUD AND ABUSE CONTROL
24 UNIT.—The term “Health Care Fraud and Abuse

1 Control Unit” means such a unit established by a
2 State in accordance with subsection (b)(2).

3 (4) INSPECTOR GENERAL.—Except as otherwise
4 provided, the term “Inspector General” means the
5 Inspector General of the Department of Health and
6 Human Services.

7 (5) RESERVE SUBACCOUNT.—The term “Re-
8 serve Subaccount” means the Health Care Fraud
9 and Abuse Reserve Subaccount of the Account.

10 (j) EFFECTIVE DATE.—

11 (1) IN GENERAL.—Except as provided in para-
12 graph (2), this section shall take effect on January
13 1, 1997.

14 (2) DEVELOPMENT AND PUBLICATION OF DE-
15 Scription OF PROGRAM.—Subsection (a)(3)(A)
16 shall take effect on the date of the enactment of this
17 Act.

Mr. SHAYS. Thank you, Mr. Chairman.

Displayed here today could be the health care equivalent of the infamous \$600 toilet or the \$7,600 coffeemaker. This year Medicare will spend \$178 billion. More than half that amount will pay for doctors, home health services and durable medical equipment. When so much money flows to one sector of the economy, abuses will occur. It happens in the Defense Department; it happens in education and housing programs; it will continue to happen in Medicare and Medicaid unless we become more vigilant in waging war against health care waste, fraud, and abuse.

The House has twice passed strong new weapons against health care fraud. Our subcommittee colleague, Representative Schiff of New Mexico, and I pushed hard for inclusion of new antifraud provisions like those before us today in the Medicare Preservation Act and in the recently passed Health Care Availability and Affordability Act, H.R. 3103. We have every reason to hope strengthened criminal sanctions and enhanced civil penalties, including lengthy exclusion of fraudulent vendors, will be included in the final conference bill.

But more can and must be done. As the General Accounting Office observed, "Certain characteristics of the Medicare program and the way it is administered create a climate ripe for abuse." Nowhere is that ripeness more apparent than in the sweet, higher than market prices Medicare pays for many goods and services. Like bees to nectar, unscrupulous vendors are drawn to exploit Medicare prices kept artificially high by an absurdly bureaucratic pricing system.

It should take months, not years—I'm going to say that again—it should take months, not years for the Health Care Finance Administration, HCFA, to effect a price adjustment under the statutory inherent reasonableness authority. Today we will hear examples of Medicare's excessive and inflexible reimbursement rates and testimony on a proposal to shorten the Medicare price adjustment process.

Medicare is also vulnerable to waste and abuse because program protections are not as aggressive or as well focused as the increasingly sophisticated schemes perpetrated against the program. The legislation before us today represents a bipartisan consensus on the need to dedicate resources to protect against Medicare fraud.

Representative Towns, our distinguished ranking member of the committee I chair, has introduced H.R. 1850, directing Health and Human Services and the Inspector General of that Department to establish a coordinated antifraud enforcement plan. His bill would also create a health care fraud and abuse control account, funded by fines and penalties, to ensure that Federal enforcement capabilities keep pace with increased Medicare spending.

Representative Schiff's bill, H.R. 3224, of which I am a primary co-sponsor, takes a similar approach. While the legislation proposed by our colleague from New York, Representative Quinn, H.R. 2480, would focus antifraud enforcement in the hands of a separate Inspector General for the Medicare program. Each approach should be considered carefully as we continue to look for new ways to stem the flow of billions—billions—of Medicare dollars now lost to fraud and abuse.

This is the second joint hearing of the Human Resources Subcommittee and the Government Management, Information, and Technology Subcommittee to discuss management of the Medicare program. As then, our united effort today reflects the importance all our Members attach to the protection of Medicare and the fight against health care fraud.

I am grateful to Chairman Horn and his ranking member, Mrs. Maloney, for their diligent and thoughtful work on these issues, as well as my colleague, Mr. Towns, and Mr. Schiff, who has been really a leader in this for many, many years. And I look forward to the testimony of all of our witnesses.

[The prepared statement of Hon. Christopher Shays follows:]

ALLAN D. ROSS JR. PENNSYLVANIA
CHAIRMAN

ONE HUNDRED FOURTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

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STATEMENT OF REP. CHRISTOPHER SHAYS MAY 2, 1996

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The House has twice passed strong new weapons against health care fraud. Our subcommittee colleague Rep. Schiff of New Mexico and I pushed hard for inclusion of new anti-fraud provisions, like those before us today, in the Medicare Preservation Act, and in the recently passed Health Care Availability and Affordability Act (H.R. 3103).

We have every reason to hope strengthened criminal sanctions and enhanced civil penalties, including lengthy exclusion of fraudulent vendors, will be included in the final conference bill.

But more can and must be done. As the General Accounting Office (GAO) observed, "certain characteristics of the [Medicare] program and the way it is administered create a climate ripe for abuse." Nowhere is that ripeness more apparent than in the sweet, higher than market prices Medicare pays for many goods and services.

Like bees to nectar, unscrupulous vendors are drawn to exploit Medicare prices kept artificially high by an absurdly bureaucratic pricing system.

Statement of Rep. Christopher Shays
 May 2, 1996
 Page 2

It should take months, not years, for the Health Care Finance Administration (HCFA) to effect a price adjustment under the statutory "inherent reasonableness" authority. Today we will hear examples of Medicare's excessive and inflexible reimbursement rates and testimony on a proposal to shorten the Medicare price adjustment process.

Medicare is also vulnerable to waste and abuse because program protections are not as aggressive or as well focused as the increasingly sophisticated schemes perpetrated against the program. The legislation before us today represents a bi-partisan consensus on the need to dedicate increased resources to protect against Medicare fraud.

Rep. Towns (D-NY), our distinguished Ranking Member, has introduced legislation, H.R. 1850, directing the Health and Human Services (HHS) Department Inspector General (IG) to establish a coordinated anti-fraud enforcement plan. His bill would also create a Health Care Fraud and Abuse Control Account, funded by fines and penalties, to ensure that federal enforcement capabilities keep pace with increased Medicare spending.

Rep. Schiff's bill, H.R. 3224, of which I am a primary cosponsor, takes a similar approach, while the legislation proposed by our colleague from New York, Rep. Quinn, H.R. 2480, would focus anti-fraud enforcement in the hands of a separate Inspector General for the Medicare program.

Each approach should be considered carefully as we continue to look for new ways to stem the flow of billions of Medicare dollars now lost to fraud and abuse.

This is the second joint hearing of the Human Resources Subcommittee and the Government Management, Information and Technology Subcommittee to discuss management of the Medicare program. As then, our united effort today reflects the importance all our Members attach to the protection of Medicare and the fight against health care fraud.

I am grateful to Chairman Horn (R-CA) and Rep. Maloney (D-NY) for their diligent and thoughtful work on these issues, and I look forward to the testimony of our witnesses.

Mr. HORN. I thank the gentleman. I see the chairman of the full committee, our distinguished leader, is here. I wonder if Mr. Clinger would like to have an opening statement.

Mr. CLINGER. I thank you very much, Mr. Chairman.

I just want to commend you and Congressman Shays and Congressman Schiff, Congressman Towns, all of the authors, and our good friend, Congressman Quinn, who have been working in this field so very, very diligently for such a long period of time.

I commend you for holding this joint hearing, which I think emphasizes the importance that we place on this. I think, as you have indicated, the reason we are here today conducting this joint hearing is to review the three principal bills that have been introduced to address the health care fraud and abuse. I am a co-sponsor of one of these bills, but I think all of them make valuable contributions and have very interesting and creative suggestions of how we can begin to address some of the problems.

One point that I, the chairman of the full committee, wanted to stress today is that the committee is serious, dead serious, about addressing this problem of health care fraud and abuse. We're not just talking the talk; we intend to walk the walk, as well.

As you have indicated, we have had a lot of hearings on this committee, and efforts to attach fraud and abuse provisions to legislation before the House are ongoing, and I think we will be ultimately productive. Everybody who has been involved really deserves a great deal of credit.

I think you have already indicated some of the sort of daunting statistics and facts that make this exercise so terribly important. GAO estimates that 10 percent of every health care dollar spent by the Federal Government goes toward wasteful or fraudulent activity. The Medicare program alone loses \$50 million a day to health care fraud.

We have just recently heard more recent projections of the rate at which the Medicare program is going down the tubes. The time of projected bankruptcy has been accelerated. It is anticipated that the system, without change, will go bankrupt in 5 years and a \$444 billion Medicare deficit by the year 2006. So, given those awesome facts, we cannot afford to delay action on this serious issue of fraud. We need, obviously, to address this if we are not to precipitate draconian cuts in the provision of medical care to this country.

You have reviewed the bills that have been offered on this matter. As I say, I think they all make constructive suggestions. I want to again comment on the importance of advancing health care fraud and abuse legislation this year. Fraudulent activity not only drives up the cost of the Medicare and Medicaid programs but also makes it increasingly difficult for all individuals to afford quality health care.

If we are really serious about controlling the rate of growth in Medicare and also about making health care more affordable generally, then now is the time to move antifraud legislation. That's why I want to commend you two subcommittee chairmen for holding this absolutely critical and important hearing this morning.

Thank you.

[The prepared statement of Hon. William F. Clinger, Jr., follows:]

Opening Statement of William F. Clinger, Jr.
Chairman

Committee on Government Reform and Oversight
Subcommittee on Government Management, Information and Technology
and Subcommittee on Human Resources and Intergovernmental Relations
Hearing on H.R. 3224 - The Health Care Fraud and Abuse Act of 1996
May 2, 1996

At the outset, I would like to commend Chairman Shays, Chairman Horn, Congressman Schiff, Congressman Towns, and all others who have worked to bring the subject of health care fraud before the *Government Management, Information and Technology and Human Resources and Intergovernmental Relations* Subcommittees.

The reason we are here today conducting a joint hearing of these two Subcommittees is to review three bills that address health care fraud and abuse. I am a cosponsor of one of the bills, H.R. 3224 -- the *Health Care Fraud and Abuse Act of 1996*. While all three bills vary in their scope and approach to the issue of health care fraud and abuse, each aims to achieve the common goal of cracking down on waste and fraud in the Medicare and Medicaid programs. And it is with this common goal in mind that we must continue to work to move forward on this issue.

One point I truly want to stress today is that this Committee is serious about addressing the problem of health care fraud and abuse. Countless hearings have been held by the Committee, and efforts to attach fraud and abuse provisions to legislation before the House are ongoing. I again want to commend all those who have worked tirelessly to advance this issue in a bipartisan manner.

As most who are gathered here today know, the General Accounting Office (GAO) estimates that 10% of every health care dollar spent by the federal government goes toward wasteful or fraudulent activities. The Medicare program alone loses \$50 million a day to health care fraud. With the Congressional Budget Office now projecting Medicare will go bankrupt in just five years and a \$444 billion Medicare deficit by 2006, we simply cannot afford to delay action on this serious issue any longer.

Despite these alarming facts, the government has not taken full advantage of anti-fraud statutes which allow the government to "exclude" fraudulent

providers from participating in the Medicare program. It simply makes no sense to continue doing business with someone who has knowingly defrauded the government.

One of the bills before us today -- H.R. 3224 -- would add new mandatory exclusions from Medicare and Medicaid for felony convictions related to health care fraud. The bill would also establish, for the first time, health care fraud as a federal crime and set out specific penalties for perpetrating fraud. When we can demonstrate to habitual offenders that exclusion and jail time are real possibilities, then I believe we will have more success fighting fraud.

H.R. 3224 also calls for coordination between the Inspectors General, Attorney General and State agencies to establish a joint program to prevent, detect and control health care fraud. Increased coordination between all responsible agencies would enable the government to have significantly greater success in fighting fraud.

Finally, the *Health Care Fraud and Abuse Act* is also concerned with the present, awkward system at the Health Care Financing Administration (HCFA) that calls for time consuming and wasteful procedures which add unnecessarily to the taxpayer's burden. H.R. 3224 requires the Secretary of Health and Human Services to adjust prices of durable medical equipment in a timely manner to allow the Medicare program to take advantage of lower market prices. I understand that today's testimony will shed some light on this very matter.

I want to again comment on the importance of advancing health care fraud and abuse legislation this year. Fraudulent activity not only drives up the cost of the Medicare and Medicaid programs, but also makes it increasingly difficult for all individuals to afford quality health care. If we are serious about controlling the rate of growth in Medicare and also about making health care more affordable generally, then now is the time move anti-fraud legislation.

I want to thank Chairman Shays and Chairman Horn one more time for conducting this hearing today, and I look forward to reviewing the testimony of the witnesses.

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Mr. HORN. I thank the chairman.

Before calling Mr. Schiff, I will just mention one more figure we might throw in. A few months ago, I was talking to the Inspector General of Health and Human Services, and she noted that her office had collected \$8 billion in Medicare and Medicaid fraud the preceding year. So I think, taking the suggestions of the various Members we have noted who have legislation in on this area, with full focus, we might well find the GAO estimate of 10 percent is an understatement, not an overstatement.

I now yield to the distinguished vice chairman of the full committee, Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I will be brief, because I know individuals are waiting to testify. But this is such an important subject, I would like to take a minute here.

We all know that the rate of increase in expenditures for Medicare cannot be sustained in the future. If we cannot find a way to bring the—not reduce the expenses of Medicare, but to reduce the rate of growth to stay in line with revenue projections, in the very near future there simply will not be a Medicare program. I mean, it literally will go bankrupt. And I don't believe that is an alarmist statement. I think the information we have received from the administration, monitoring the Medicare expenditures, more than bears that out.

The challenge for Congress is to find ways to bring Medicare costs under control without reducing the services to Medicare beneficiaries and without reducing the reasonable rate of payment to those who provide health care services to Medicare beneficiaries. I think there are a number of ways we can do it.

One way is to take a closer look at the reimbursement rates and how they are figured, which is the main subject of this hearing, in which my colleague, Congressman Shays, has been the leader here in the Congress, along with yourself, Mr. Chairman.

Second, I believe that we can do much more to bring fraud and abuse under control. I have introduced a bill, which is also a subject here, with Congressman Shays, and with Congressman Towns in the last Congress, that would provide improvements, in my opinion, in the ability of the Federal Government to investigate and prosecute fraud.

I am very happy to say that the major provisions of that bill are currently in H.R. 3103, which is the House version of the health care reform legislation that is pending between the House and the Senate right now. I am hopeful that we will achieve a final bill. I am hopeful those provisions will remain. The reason for refileing a bill is in case something goes wrong with the current health care reform bill and nothing is passed, that we still have a vehicle to approach this serious problem.

I think that, with relatively little effort, we can bring about great results, because the amount of fraud and abuse that is occurring in the situation is so great that I believe taking even moderate measures can bring an enormous savings to the program.

Thank you very much, Mr. Chairman.

Mr. HORN. Thank you.

Before calling on the ranking minority member, I would ask the gentleman from Illinois, Mr. Hastert, if he has an opening statement.

Mr. HASTERT. I thank the chairman.

Just very briefly, as you know, I have been kind of the point man on health care around this place for a while. Health fraud and abuse accounts for every \$1 out of \$10 that either the Federal Government spends, individuals spend, or insurance companies spend. We need to get a handle on it. We did include a version of Mr. Schiff's bill in the health care reform package that passed the House overwhelmingly and now is awaiting work between the House and the Senate.

This is a very important issue. I am pleased to be able to sit in with you for a little while today and hear your testimony. Thank you.

Mr. HORN. Thank you.

I now yield to the gentleman from New York, Mr. Towns. In the last Congress he, as a subcommittee chairman, was extremely active in pursuing waste, fraud, and abuse. I remember our subcommittee went to New York, where substantial fraud and abuse was found and a few indictments were filed.

Mr. TOWNS. Thank you very much, Mr. Chairman, for your outstanding leadership in this area. I also would like to thank Congressman Shays, as well, for his work on this.

I think that there is no doubt about it, fraud and abuse is a very serious issue, and it should be addressed in that fashion. H.R. 1850 and H.R. 3224 are the results of several oversight hearings in the Human Resources and Intergovernmental Relations Subcommittee, initiated during my chairmanship in the 103d Congress and carried forward, of course, by Chairman Shays.

H.R. 1850 took us the first step toward the Federal control of health care fraud. However, I think that H.R. 3224, inclusion of the Attorney General in the coordination of Federal enforcement efforts in Title I, revisions to criminal law in Title II, and antifraud initiatives under the Medicare and Medicaid programs in Title III take us a great deal further. And I think that we should go as far as we can.

I commend Subcommittee Member Schiff, too, of course, for his work in this, as well. When I was chair, he was the ranking.

However, despite my enthusiasm for H.R. 3224, I have some reservations that prevent me from giving my total support at this particular time. In an earlier legislative hearing, concerns were raised about provisions of H.R. 3224, the predecessor bill, that do not appear to have been corrected in the current bill, and I am concerned about that.

Let me just give one example that comes to mind in the Department of Justice objection to a Title II provision that equal authority over investigative demand procedures to the Attorney General and the Director of the FBI, an agency within the Justice Department. I look forward to working toward a bipartisan resolution to this and other concerns about the bill, because I think that we need to make certain that this issue is very clear as to who is responsible for what.

Finally, Mr. Chairman, I welcome our witnesses today: of course, my colleague from the State of New York, who has been very active in this matter, Congressman Quinn from upstate New York and the author of the third bill under consideration today. I would like to personally commend him for his outstanding work in this regard. He has indicated that he would like to see fraud and abuse disappear, because if we are going to try to balance the budget, we need to find all the dollars that we can get.

So I would like to say to you, Mr. Quinn, we appreciate your leadership.

Of course, I look forward to all the other witnesses, in terms of the information they might have to be able to work with us to eliminate fraud and abuse, which is a very serious problem, and it has been demonstrated as we have had hearings around this country.

So, Mr. Chairman, on that note, I yield back.

[The prepared statement of Hon. Edolphus Towns follows:]

OPENING STATEMENT OF REP. ED TOWNS
BEFORE THE GOVERNMENT REFORM AND OVERSIGHT
SUBCOMMITTEE ON
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

Legislative Hearing

H.R. 1850, the "Health Care Fraud and Abuse Act of 1995"

H.R. 3224, the "Health Care Fraud and Abuse Prevention Act of 1996"

H.R. 2480, the "Inspector General for Medicare and Medicaid Act of 1995"

May 2, 1996

CHAIRMAN SHAYS, CHAIRMAN HORN, THANK YOU FOR
CONVENING THIS JOINT HEARING TO CONSIDER THREE
LEGISLATIVE PROPOSALS: H.R. 3224, H.R. 2480, AND H.R. 1850 -- A
BILL I INTRODUCED LAST JUNE. THESE BILLS SHARE A COMMON
AND IMPORTANT OBJECTIVE, TO CONTROL THE RAMPANT WASTE,
FRAUD AND ABUSE IN MEDICARE AND MEDICAID PROGRAMS.

THE GENERAL ACCOUNTING OFFICE ESTIMATES THAT 10
PERCENT OF U.S. HEALTH CARE SPENDING, WHICH COULD
POSSIBLY BE AS MUCH AS 100 BILLION DOLLARS, IS LOST
ANNUALLY TO HEALTH CARE FRAUD AND ABUSE. OF THAT
AMOUNT, ONE QUARTER -- 25 BILLION DOLLARS MAY BE LOST TO
FRAUDULENT AND ABUSIVE PRACTICES IN MEDICARE AND
MEDICAID.

FROM A FISCAL PERSPECTIVE, IT IS OBVIOUS THAT CONTROLLING THIS PROBLEM CAN SAVE BILLIONS OF TAXPAYER DOLLARS. IN ADDITION, THE FAILURE TO REDUCE THESE LOSSES CAN NO LONGER BE SUSTAINED IN THE FACE OF PENDING CUTS AND SHORTFALLS IN MEDICARE AND MEDICAID.

BUT EQUALLY IMPORTANT, THE SYSTEMIC CORRUPTION OF THESE PROGRAMS PERPETRATED BY CRIMINAL PROVIDERS UNDERMINES THE QUALITY OF HEALTH CARE AVAILABLE TO MEDICARE AND MEDICAID BENEFICIARIES -- THE POOR, THE ELDERLY, AND THE DISABLED -- VICTIMIZING THE MOST VULNERABLE OF AMERICA'S CITIZENS.

H.R. 1850 AND H.R. 3224 ARE THE RESULT OF SEVERAL OVERSIGHT HEARINGS IN THE HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE -- INITIATED DURING MY CHAIRMANSHIP IN THE 103RD CONGRESS, AND CARRIED FORWARD BY CHAIRMAN SHAYS. THESE HEARINGS ESTABLISHED THE EXTENT OF FRAUD AND ABUSE IN THE FEDERAL HEALTH CARE SYSTEM, THE EFFECTIVENESS OF CURRENT ENFORCEMENT EFFORTS, AND OPPORTUNITIES THAT EXIST, AS WELL AS THOSE WHICH MUST BE CREATED, TO IMPROVE ENFORCEMENT OF FRAUD AND ABUSE VIOLATIONS.

H.R. 1850 TOOK US THE FIRST STEP TOWARD IMPROVING THE FEDERAL CONTROL OF HEALTH CARE FRAUD. HOWEVER, I THINK THAT H.R. 3224'S INCLUSION OF THE ATTORNEY GENERAL IN THE COORDINATION OF FEDERAL ENFORCEMENT EFFORTS IN TITLE 1, REVISIONS TO CRIMINAL LAW IN TITLE 2, AND ANTI-FRAUD INITIATIVES UNDER THE MEDICARE AND MEDICAID PROGRAMS IN TITLE 3 TAKE US A GREAT DEAL FURTHER. I COMMEND SUBCOMMITTEE MEMBER SCHIFF AND CHAIRMAN SHAYS FOR THEIR WORK IN DEVELOPING H.R. 3224, AND FOR INCORPORATING MY BILL INTO TITLE 1 OF THEIR LEGISLATION.

HOWEVER, DESPITE MY ENTHUSIASM FOR H.R. 3224, I HAVE SOME RESERVATIONS THAT PREVENT ME GIVING IT MY UNBIASED SUPPORT. IN AN EARLIER LEGISLATIVE HEARING, CONCERNS WERE RAISED ABOUT PROVISIONS OF H.R. 3224'S PREDECESSOR BILL THAT DO NOT APPEAR TO HAVE BEEN CORRECTED IN THE CURRENT BILL. ONE EXAMPLE THAT COMES TO MIND IS THE DEPARTMENT OF JUSTICE'S OBJECTION TO A TITLE 2 PROVISION THAT CONFERRED EQUAL AUTHORITY OVER INVESTIGATIVE DEMAND PROCEDURES TO THE ATTORNEY GENERAL AND THE DIRECTOR OF THE FBI -- AN AGENCY WITHIN THE JUSTICE DEPARTMENT.

I LOOK FORWARD TO WORKING TOWARD A BIPARTISAN RESOLUTION TO THIS AND OTHER CONCERNS ABOUT THE BILL.

FINALLY, I WELCOME OUR WITNESSES, PARTICULARLY CONGRESSMAN JACK QUINN OF NEW YORK, THE AUTHOR OF THE THIRD BILL UNDER CONSIDERATION TODAY. I APPRECIATE AND APPLAUD THE INTENT OF HIS BILL TO ENHANCE FEDERAL ENFORCEMENT EFFORTS. ALTHOUGH I AM NOT CONFIDENT THAT THE APPROACH PROPOSED BY THIS LEGISLATION -- THE CREATION OF A NEW KIND OF INSPECTOR GENERAL -- IS SUPPORTED BY OUR EXAMINATION OF THE ISSUES, I LOOK FORWARD TO THE TESTIMONY OF MY ESTEEMED COLLEAGUE, AS WELL AS THAT OF ALL OF OUR WITNESSES, WITH AN OPEN AND INTERESTED MIND.

Mr. SCHIFF. Would the gentleman yield for just 1 second?

Mr. TOWNS. I would be delighted to yield to the gentleman from New Mexico.

Mr. SCHIFF. Mr. Chairman, may I beg your indulgence for just 1 second?

I just want to say that, during the period we have been working on this bill, in the last Congress, with yourself, and this Congress, we have worked very closely with the Justice Department. We took care of most of their objections. They have brought to my attention one or two more where I think they are right. I think, if this bill proceeds, we should address their concerns.

I have not heard that objection. So I don't know if the FBI or Justice Department are represented here at this hearing. I would hope they are. But, if not, I would like to communicate with them and invite you to, Congressman Towns, bring to all of us whatever remaining concerns they have. They are the law enforcement agency of this country, and I certainly want to work very closely with them in fashioning legislation that deals with law enforcement. I just want to make that point clear.

Mr. TOWNS. Right. The point, though, that I am trying to make is that the FBI is in the Justice Department, and I think that's the point. So we need to make certain that that is clear.

Mr. SCHIFF. Well, I wasn't disagreeing, I'm just saying that's not one the Justice Department has mentioned to me recently, and I am willing to listen to any objection that they have.

Mr. TOWNS. Well, I'm happy the gentleman has an open mind. So I'm certain, if he has an open mind, we will be able to work this out. With that in mind, yield back, because I don't want him to close his mind.

Mr. HORN. Thank you.

Before calling on Mr. Shays, I will note that the Justice Department ought to go through it and put in writing all of their objections so we have them in one place and can deal with it, and not have a nickel and dime operation on amendments.

I now yield to my colleague, Chairman Shays.

Mr. SHAYS. Thank you.

Mr. Quinn, I know you are prepared to testify. I wanted to thank Mr. Hastert for the work that he does. One of the problems that we have had in the past is, we have three committees that focus on health care: You have Ways and Means, you have Commerce, you have this Government Reform Committee. It has been very important to have Mr. Hastert coordinate that activity.

I particularly appreciate the fact that what Mr. Schiff and others have been working on, making health care fraud a Federal offense and also making it an all-payer system is in the health care bill in both the House and Senate. So there is absolutely no reason why we shouldn't expect that it will make the conference report, since it is in both bills.

I thank the gentleman.

Mr. HORN. I thank you.

I notice that our principal witness has turned gray since coming into this hearing, with the number of opening statements. But it's always a pleasure to see my colleague, Mr. Quinn of New York, and he has put a tremendous amount of effort in on this problem.

We are delighted to have you as our first witness.
The gentleman from New York.

**STATEMENT OF HON. JACK QUINN, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF NEW YORK**

Mr. QUINN. Thank you, Mr. Chairman.

I would like to thank you for calling today's hearing and thank Mr. Towns for his kind words, Mr. Shays and Mr. Schiff for their help, guidance, and advice with our staff these last few months on my bill that I'm going to talk about a few minutes this morning. I also thank Mr. Hastert for his work for many, many years. Long before I came here and turned gray, Mr. Chairman, Mr. Hastert was working on this issue.

And I also thank Mr. Clinger, who I've had the opportunity, within the committee, to work with these last couple years on the Line Item Veto, for one thing. I want to say for the record that Mr. Clinger, who has announced his retirement from the House, is going to be missed very, very much on this committee as well as the full membership on both sides of the aisle.

Bill, thanks for your help.

Also, with your indulgence, Mr. Chairman, thank you. As classmates here in this Congress, you and I came together and have worked on, I think, this whole waste, fraud, and abuse question since we came here.

I would like to, before I begin testimony, announce to the Members that we have some special visitors here today. I would like to welcome the students of School 45 from Buffalo, NY, who are here visiting the Nation's Capital this weekend, and the staff, and Mr. Chairman, Mr. Horn, through your indulgence, has been able to allow them into a hearing.

I would say to the students, it's not often—although the students are around the Capital and take tours of the buildings, and so on and so forth, it's a very rare opportunity that you are able to be in and to participate at a hearing of this magnitude, where we're talking about what we're going to do with Medicare and how it's going to be reformed to affect the whole country. So it's a good day to be off school, but you're being let in on probably a great opportunity here today. And I'll try not to bore these young students, nor bore the committee, so I will get on with this testimony.

I am particularly pleased to be here this morning and taking an active role in this discussion and a chance, in a brief 5 or 10 minutes or so, to present my bill, H.R. 2480, the Inspector General for Medicare and Medicaid Act of 1995 for your consideration in this overall discussion. I also want to take the opportunity to thank the IG from HHS, who has been in our office these last couple of weeks talking about the bill and talking about your activity.

I was prompted to introduce this legislation last year when seniors in western New York seemed to approach me almost every single weekend and at our town meetings last year about their concerns related to this issue. Many of us in Congress, and throughout the country, share these concerns of waste, fraud, and abuse, and we know that it has almost reached an excessive level which threatens the very financial stability of those most vulnerable in our populations across the country.

For instance, one of my constituents gave me copies of his personal medical statements which showed that he was billed three times for the same procedure. It amounted to \$2,367. Now, many people don't scrutinize these statements, don't have the help to scrutinize those, and they are easily overlooked, forcing seniors sometimes to dip into their life savings.

A brief description of the bill, H.R. 2480, would be as follows: I suggest that we establish an exclusive, full-time, and independent Office of the Inspector General for Medicare and Medicaid Programs. The office would be charged with detecting, identifying, and preventing waste, fraud, and abuse within both the Medicare and Medicaid programs, pretty much what they are doing right now.

The Medicare and Medicaid IG would be appointed by the President with the advice and consent of the Senate. My point to make here is that the Medicare and Medicaid IG would be ultimately accountable to the President of the United States.

This IG office would also be required to issue semiannual reports to the Congress, consisting of recommendations on preventing waste, fraud, and abuse within the programs. The IG office would also be responsible for coordinating audits, investigations, and other activities which promote efficiencies in the administration of the programs.

Funding levels for the IG office to execute its duties would be determined by the authorization and appropriations committees with jurisdictions. The Congressional Budget Office has estimated enactment of this bill, 2480, to affect discretionary spending by \$1 million annually. That may sound like an awful lot of money, particularly to the youngsters here from School 45, in Buffalo, NY, but, as we will point out later, a dollar spent for this kind of activity brings back returns many, many times over.

The need for this legislation comes down to dollars and cents, ladies and gentlemen. It is as clear as anything else that we have talked about regarding Medicaid and Medicare. According to a 1995 GAO report, unchecked and improper billing alone could cost Medicare in excess of \$3 billion over the next 5 years.

Furthermore, health fraud has been estimated to cost between 3 percent and 10 percent of every dollar used to meet the health needs of America's seniors and indigent populations. I think you would agree that this funding would be better spent as a reinvestment, providing health care to our Nation's elderly, disabled, and poor citizens.

To further compound the problem, the GAO also reported that physicians, suppliers, and medical laboratories have about 3 chances out of 1,000 of having Medicare audit their billing practices in any given year. In my brief discussions with the IG just 2 weeks ago in my office, I understand that those percentages are becoming better. Indeed, the results of the money that is returning is getting higher, and I want to compliment the IG for the great job that they are doing.

At the conclusion of the July 1995 GAO report to Congress, one of the main policy recommendations was to "enhance Medicare's antifraud and abuse efforts." My bill simply responds to this need. I contend that with a separate IG office we can only expand on

identifying and preventing fraud, waste, and abuse in the health care system.

Based on HHS data, within a 4-year timeframe, we have saved \$115 for every dollar spent on the Inspector General operations. We have saved \$115 for every dollar spent. In 1995, the Office of the IG saved \$9.7 million per employee. That's what I meant when I said, a few moments ago, that that outlay that we talked about might seem like a lot of money, but I believe we get it back in a big way.

This savings was accomplished with employees working on diversified caseloads. And it is my understanding that the employees at the IG office do not specialize in Medicare and Medicaid fraud but must focus on several issues at one time. With more specialized personnel, other HHS programs, such as welfare and Head Start, stand to benefit, as well. By magnifying our focus to Medicare and Medicaid fraud, waste, and abuse, I am confident that we will see an increased return on this investment.

The Social Security Act of 1994 serves as a precedent for this legislation. Due to a congressional recommendation, the Social Security Administration became an independent agency with its own Inspector General office charged with oversight of its activities. For the fiscal year of 1996, the Social Security Administration's Office of the Inspector General received an appropriation of almost \$26 million.

As a member dedicated to congressional reform and eliminating wasteful Government spending, I appreciate the opportunity to work with others who share this goal to channel our greater resources toward investigating and ultimately terminating waste, fraud, and abuse in Medicare and Medicaid programs.

Aside from the proposed bill that I've spent the last 4 or 5 minutes talking about with you this morning, I also support alternative efforts which help us to achieve this goal in a bipartisan way. Mr. Chairman, I am a co-sponsor of your legislation, H.R. 3224, the Health Care Fraud and Abuse Act of 1996. As I mentioned, I also met with the Inspector General for the HHS Department, June Gibbs Brown. I am pleased to learn that the agency is currently increasing their attention to antifraud projects which specifically concern Medicare and Medicaid.

As the red light goes on, and in my effort to keep your time well spent here this morning, I thank the chairman and thank the full committee for hearing my testimony this morning and also look forward to working with everyone on the committee and in the House.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Jack Quinn follows:]

JACK QUINN
30TH DISTRICT, NEW YORK

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Congressman Jack Quinn, R-NY

H.R. 2480 -- "The Inspector General for Medicare and Medicaid Act of 1995"

Testimony Before the House Government Reform & Oversight

Subcommittees on

Human Resources and Intergovernmental Relations

and

Government Management, Information and Technology

Joint Hearing on Health Care Fraud and Abuse

May 2, 1996

Good morning Mr. Chairman. I am pleased to be here today. I thank the committee and your staff for holding this hearing to examine fraud, waste and abuse in our national health care system.

I am particularly pleased to be taking an active role in this national discussion by presenting my bill H.R. 2480, the "Inspector General for Medicare & Medicaid Act of 1995," for consideration in this hearing.

I was prompted to introduce this legislation when seniors in Western New York continuously approached me at my town meetings last year with concerns about this issue. Many of us in Congress and throughout the country share their concerns that waste, fraud, and abuse within Medicare and Medicaid programs have reached an excessive level which threatens the financial stability of our most vulnerable populations.

For instance, one of my constituents gave me copies of his personal medical statements which showed that he was billed three times for the same procedure, amounting to \$2,367 in charges. Many people do not scrutinize their statements and situations such as these are easily overlooked -- forcing seniors to dip into their life savings.

My bill would establish an exclusive, full-time and independent Office of Inspector General (IG) for the Medicare and Medicaid programs. This office would be charged with detecting, identifying and preventing waste, fraud and abuse within the Medicare and Medicaid Programs.

The Medicare and Medicaid IG would be appointed by the President, with the advice and consent of the Senate. My point is that the Medicare and Medicaid IG would be ultimately accountable to the President of the United States.

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This IG office would also be required to issue semi-annual reports to Congress consisting of recommendations on preventing waste, fraud and abuse within the Medicare and Medicaid programs.

The IG office would also be responsible for coordinating any audits, investigations, and other activities which promote efficiency in the administration of the Medicare and Medicaid programs.

Funding levels for the IG office to execute its duties would be determined by the authorization and appropriations committees with jurisdiction.

The Congressional Budget Office has estimated enactment of H.R. 2480 to affect discretionary spending by \$1 million annually.

The need for this legislation comes down to dollars and cents ladies and gentlemen. According to a 1995 GAO report, unchecked and improper billing alone could cost Medicare in excess of \$3 billion over the next five years. Furthermore, health fraud has been estimated to cost between 3-10% of every dollar used to meet the health needs of America's seniors and indigent populations. I think you would agree that this funding would be better spent as a reinvestment in providing healthcare to our nation's elderly, disabled and poor citizens.

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To further compound the problem, GAO also reported that physicians, suppliers, and medical laboratories have about three chances out of 1,000 of having Medicare audit their billing practices in any given year.

At the conclusion of the July, 1995 GAO report to Congress, one of the main policy recommendations was to "enhance Medicare's anti-fraud and abuse efforts."

My bill simply responds to this need. I contend that with a separate IG office we can only expand on identifying and preventing fraud, waste, and abuse in healthcare. Based on HHS data, within a four-year time frame, we have saved \$115 for every dollar spent on Inspector General operations. In 1995, the Office of the IG saved \$9.7 million per employee. This savings was accomplished with employees working on diversified case loads. It is my understanding that employees in the IG's office do not specialize in Medicare and Medicaid fraud, but must focus on several issues at one time. With a more specialized personnel, other HHS programs such as welfare and head start stand to benefit as well. By magnifying our focus to Medicare and Medicaid fraud, waste, and abuse, I am confident that we will see an increased return of our investment.

The Social Security Reform Act of 1994 serves as a precedent for my legislation. Due to a Congressional recommendation, the Social Security Administration (SSA) became an independent agency with its own Inspector General Office charged with oversight of its activities. For Fiscal Year 1996, the SSA's Office of the Inspector General received an appropriation of \$25.9 million.

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Medicare is the nation's largest single payer of health care costs, representing 14 percent of the federal budget and spending \$162 billion in 1994. The Omnibus Appropriations Act, just passed by Congress and signed by the President, appropriates \$197.4 billion for HHS programs. The Inspector General's annual budget is \$79.162 million. This budget is more than three times the size of the Social Security Administration's appropriation for IG functions. It is clear therefore, that any Office of Inspector General for Medicare and Medicaid needs additional resources to get the job done.

As a member dedicated to Congressional Reform, and eliminating wasteful government spending, I appreciate working with others who share my primary goal to channel greater resources toward investigating and ultimately terminating fraud, waste and abuse in Medicare and Medicaid programs. Aside from my proposed bill, I support alternative efforts which help us to achieve our goal. Mr. Chairman, I am a co-sponsor of your legislation, H.R. 3224, the "Health Care Fraud & Abuse Act of 1996." I have also met with the Inspector General for the Department of Health and Human Services, June Gibbs-Brown, and am pleased to learn that the agency is currently increasing their attention to anti-fraud projects which specifically concern Medicare and Medicaid.

Once again, thank you for involving me in this most important discussion.

I look forward to coordinating our efforts to accomplish health care reform.

I also look forward to reviewing the next Inspector General Semi-Annual report due this September in order to evaluate the effectiveness of the newly instated, anti-fraud projects.

I will be happy to answer any questions you may have.

Mr. HORN. Thank you very much for those helpful comments. Have you had an opportunity to read the other bills that are before this committee on this issue?

Mr. QUINN. Yes, Mr. Chairman, I have.

Mr. HORN. As I understand it, basically what you would do is follow the Inspectors General Act and simply create a separate Inspector General for Medicare and Medicaid; is that correct?

Mr. QUINN. Yes, Mr. Chairman.

Mr. HORN. Did you notice that some additions have been made in these other bills? And I just wonder what you thought of them and whether they ought to be incorporated in any bill that is reported from this committee.

Mr. QUINN. Mr. Chairman, I think the additions that you speak of are all positive steps in the right direction. As a matter of fact, when we dropped this bill last year, we began to look at some of the other action that was taken here in the House. I want you to know that I am a firm believer that we don't need to replicate or duplicate each other's efforts here.

I think that the other bills you will hear about this morning, indeed, work that has been done in the previous Congress, Mr. Towns' efforts, are all headed in the right direction. My only concern here is that we allow the Inspector General, right now part of another department, to put as much effort and resources as possible to getting rid of waste, fraud, and abuse.

The IG said to me, Mr. Chairman, in our meeting in the office that she was so gracious to attend and stayed for quite some time, that may be the solution, is to provide more resources to the office as it is operating right now. I would just like to say for the record today, while I think my bill has some merit, I am willing to work with your direction and the members of the committee to accomplish the same goal.

Mr. HORN. Well, I thank you. My own personal bias here is that they ought to have a separate IG for these areas, as you suggest. I think HHS itself, minus these programs, has plenty of other problems to deal with, and it would give that office greater focus. But you are right, we ought to be willing to invest in the resources if we're going to get the return for the taxpayers that is clearly out there.

Now, some other proposals have been made to urge senior consumers, in particular, to read their bills, and so forth. Do you have some suggestions along that line, such as giving them a reward for turning in waste, fraud, and abuse, et cetera?

Mr. QUINN. Yes, Mr. Chairman, I would agree with all of those suggestions. I want to tell you that, as we drafted the bill, one of the things we did in the office, in Buffalo, was to call the hotline, was to call the waste, fraud, and abuse hotline number, a 1-800 number. And it was a challenge to wait for the number, to then be given some options, depending on what my call was about, to be transferred to another phone, and then, when I got to that phone, another number.

And finally, believe it or not, they connected me to Mr. Towns' office in New York—no, I'm only kidding. They didn't do that.

Mr. HORN. It sounds like he's starting to run Statewide.

Mr. QUINN. He was talking about some kind of benefit basketball game somewhere. I don't know what was going on.

But, seriously, Mr. Chairman, we in the office—I called the number, and then to make sure that there was somebody more intelligent than me making the call, I asked some staffers to do that. And it was a challenge. I think that, while those kinds of suggestions are good ones, the reward or other like suggestions so far, I think we need to remember, however, in most cases, we're dealing with seniors here. We can't make it too difficult for them to do that reporting, is what I'm trying to say.

My father just had a triple bypass on Thanksgiving Eve this past year, and he's doing great, feeling wonderfully, but he needed some help going through his bills. And I can just imagine, if we make that line of thinking too difficult for seniors—we need to remember the population we're talking about here in Medicaid and Medicare. I subscribe to those and support them, but I think we need to make sure they are not making it too difficult for them.

Mr. HORN. I have had doctors on cases try to translate bills for me that others have given me, because I have had your same experience. Constituents say, hey, here's this bill and, you know, 20 pages comes out of a computer, and everything but the kitchen sink has been added in there, and how they forgot that none of us quite could figure out.

But you are right. There needs to be some type of communication in simple English. And the idea of holding people on a queue of 8 minutes or so—I've tried the Social Security 800 numbers and others. They are very helpful people once you get them, but you wonder if you're ever going to get them. People think, "Gee, I must have dialed wrong or something," and they break that link.

So do you have any other comments to make on any of the other legislation that is with us here?

Mr. QUINN. I am not prepared this morning for that, Mr. Chairman, only to say that I think there's an awful lot of good legislation out there. It's your challenge, as the Chair of the subcommittee and all of the full committee members, to put something together that makes sense, for the Congress to act on then, and for the American public.

Mr. HORN. I now yield to the gentleman from New York, Mr. Towns, for questions.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me begin by thanking Mr. Quinn for his statement and also his involvement, because I think that the key here is to create the atmosphere and climate to bring about the kind of change that needs to take place. I agree with you that additional resources will have to be allocated in order to be able to do the job that needs to be done.

I think that your legislation going in sort of helps us to focus on that and to make certain that we do not forget about the importance of it. I also appreciate the fact that you said the main thing is to let us do something, you know, that you are willing to sign on and to be flexible as long as we're going in the right direction, in terms of eliminating fraud and abuse. So I appreciate your comments in that regard, as well.

The thing I was just thinking about that was raised by the chairman, in terms of some kind of initiative, what could we really do to sort of encourage—how could we structure it? We don't want it to become so cumbersome that we can't really make it work. A bounty of some sort? I don't know, in terms of what we would do. Have you thought about some things we might be able to do?

The other part, maybe, that I would like to hear your views on is that people who are caught doing something that's wrong, and then, all of a sudden, you find out that the father now is in business rather than the son, or the son is in business rather than the father, or the mother is in business now rather than the sister, and it's the same folks benefiting from fraud and abuse, but the only thing is now the name has been changed. I would just like to get your views on that, as well.

Mr. QUINN. Thank you, Mr. Towns. Thank you for the kind remarks.

I would respond in two ways. First of all, my legislation to create a separate, full-time Office of the Inspector General, instead of being part of HHS, I think sends the right message. The direct answer to your question: Some of what we can do, I believe, is public relations; in other words, let people know that there will be a full-time Inspector General's office in charge of this.

I think, once the word gets out that that's going to happen, some people who might be thinking about taking advantage of a loophole or an opportunity for waste, fraud, and abuse, if they know there's a full-time Inspector General that's going to give them a hassle about it, I think, right away, some of those opportunities will disappear.

In other words, we need a "get tough" policy. We need to spread the word that there's a "get tough" policy when you come to waste, fraud, and abuse. One of the ways to do that is to make certain that we think it's important enough that we have a full-time Inspector General that's funded properly to do it, and if you fool around with this system, you're going to get caught and you're going to be brought to justice.

So I think my suggestion, modest as it is in this bill, to have a full-time Inspector General for this area sends the right message out, that we are going to get tough. And it's full-time; it's important enough that it's not a part of HHS, it's here. It's the big time. We did it for Social Security; we're doing it in other areas. So I think that message is one of the things that we can do.

The second way I would respond to your question: In my discussions with the IG about this and her great work in it, one of the things that we need to remember is that it takes some time to get a return on this money and to bring these people to justice. You don't just say, here we found someone who was billed four or five times inaccurately or a real effort to defraud the Government—you can't just get that money back in 2 or 3 weeks, or 4 weeks.

It's got to go through the system; it's got to go through the criminal justice system, in many cases. All I would suggest, as a second answer to your question, is that, as you, as the committee looks at the bill, you also look at areas in which you can assist the IG, whether it's my bill or the existing set-up for the IG, in the criminal justice system, to make that happen in a timely way.

Mr. TOWNS. Thank you very much. I look forward to working with you in making certain that we do get some legislation that is going to help us to deal with fraud and abuse. Thank you very much for your testimony.

Mr. QUINN. Thank you, Mr. Towns.

Mr. HORN. Thank you.

I now yield to the co-chairman of this hearing, the gentleman from Connecticut.

Mr. SHAYS. Thank you.

Mr. Quinn, I look forward to working with you. As we have a hearing like this, it's hard not to be very angry about the things that we could do that would be easy. The Inspector General of HHS still is the Acting Inspector General of Social Security. We have a wonderful staff under her that does focus on Medicare but I think your point that, given \$178 billion, there is an argument to have a separate office.

One of the things we want is inherent reasonableness. We can't reprice some of the products here, so we pay more than the market price. In some cases, you can go to a drug store and buy it at a third less. So we have examples, just replete, where we have to petition the vendors, practically, to get their permission to pay a market price.

We don't have one vendor number. So we knock somebody out, and they have another vendor number, and they are still in business. So there is a lot we can do. I just appreciate the work you have already done. But, I mean, I just think we really have got to push on this.

I thank you, and I yield back my time.

Mr. HORN. Well, I might say, one of the problems is in Medicare and Medicaid itself where they sign off on these bills without too much review, in some cases. I think we need to take a look at that also.

I now yield to the gentleman, the full committee chairman, Mr. Clinger.

Mr. CLINGER. No questions, Mr. Chairman. I just want to commend and congratulate Mr. Quinn on his continued interest in and contribution to what is clearly, I think, the most important thing that we can do to ensure continuation of the Medicare system. As we have heard, it is in dire straits. The longer we permit the kind of excesses and the kind of abuse that we have seen in previous hearings in this committee, and here again, to go on, the more difficult it is going to be to solve those fundamental problems that exist in the system.

So I think you have made a very valuable contribution to the debate, and I look forward to your continued working with us as we try to move toward a solution.

Mr. QUINN. Thank you, Bill. Thanks very much.

Mr. HORN. OK. Any further comments you would like to make?

Mr. QUINN. Mr. Chairman, thank you for the reception this morning, and, again, thank you for your courtesies for the youngsters that are touring here today. We're going to show them the rest of the Capitol, but they saw Government at work this morning, and we appreciate it very, very much.

Mr. HORN. School 45, is it?

Mr. QUINN. School 45.

Mr. HORN. I want them to know that their Congressman came in our class in 1993, and he is the hardest-working Member of the class. So you can be proud of him.

Mr. SHAYS. But that still makes him, what, a sophomore?

Mr. SCHIFF. A sophomore, that's right.

Mr. QUINN. I have a ways to go here before we graduate, it seems like.

Mr. TOWNS. Mr. Chairman, why don't we just give them a little round of applause. That's OK. [Applause.]

Mr. QUINN. Well deserved for listening to me for about 15 minutes. Thank you, Mr. Chairman.

Mr. HORN. Well deserved for listening to any of us for 15 minutes.

We are going to now switch co-chairs here. Mr. Mangano, the Deputy Inspector General, will come forward to have the oath administered to him.

Mr. SHAYS. Do you have anyone else who will be testifying with you?

Mr. MANGANO. No.

Mr. SHAYS. Thank you.

[Witness sworn.]

Mr. SHAYS. The only difference from being chairman and sitting there is that the chair is up higher. That's the only difference. We will just wait a second.

Mr. TOWNS. While you're waiting, Mr. Chairman, I would like to test that height.

Mr. SHAYS. While we're waiting, I might point out that yesterday about 70 Members of Congress introduced a resolution asking, on the board of trustees of the trust fund that oversees the Medicare Trust Fund, Part A, a resolution asking the board to submit their findings, their annual report, which was due April 1 and still has not been submitted. You are going to see a bipartisan effort, I think, to get this board to do their job and submit their report, given the fact that the fund seems to be going insolvent much sooner than we thought.

With that, Mr. Mangano, I look forward to your testimony and would welcome you to give your testimony now.

STATEMENT OF MICHAEL MANGANO, PRINCIPAL DEPUTY INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MANGANO. Thank you very much, Mr. Chairman.

I really look forward this morning to talking with you about some of the proposed legislation, and more particularly about some of the problems of fraud, waste, and abuse that we have found in the Medicare equipment and supply area.

I would like to very briefly describe some of the work that we have done, to give you an indication of the range of problems and some of the solutions that we think are necessary. Most primary, we believe that some fundamental reforms are needed with the way that Medicare can purchase goods and services. Those kinds of authorities, which I will talk about in a minute or two, are abso-

lutely essential to make Medicare a more prudent purchaser of services and goods.

Because of the huge sums of money involved with the Medicare program, it is almost inevitable that at least some individuals or companies will try to unfairly take advantage of loopholes in the laws or to absolutely violate the law to enrich themselves at the expense of the American taxpayer or the Medicare beneficiaries.

Our audits, investigations, and evaluations have pinpointed a number of problems that we see consistently over time in the area of Medicare equipment and supplies. Most particularly—let me just mention a few of those—we find that some suppliers file claims for equipment that was never delivered.

Some will bill for high-cost equipment when they actually deliver something that is less expensive. We call this “upcoding.” Some will bill for the component parts of a particular piece of medical supply rather than bill for the entire product itself. We call this “unbundling.” Some will deliver equipment that actually has no therapeutic benefit to the patient. And, finally, we believe the Medicare reimbursement rates are far too high on some of the items that I will be talking about this morning.

In the last 5 years, our office has been heavily involved in this area. We have developed investigations that have produced about 145 criminal convictions and 284 exclusions. We, at the current time, have over 200 cases that are open, investigating into medical equipment and supplies.

Several factors really make this area attractive for fraud. One is the high profit margin; second, is the ease of entry into the marketplace. Until we recently got the regionalization of claims processing, Medicare simply was too loose in the way that they paid their bills.

The most important message I would like to leave today with this committee is that the Medicare program is far too limited in how they can act and how quickly they can act. We believe that the Medicare program needs four new authorities through legislation that will enable them to really control better this area of medical supplies and equipment.

First, when HCFA and the Inspector General, identify a particular piece of equipment that is just overpriced or what we would call “inherently unreasonable,” Medicare can’t really react fast enough to the marketplace to adjust that price downward. Instead, they have to use, at the current time, the rulemaking process, which usually takes about 2 to 4 years. It is time-consuming and resource-intensive.

Mr. Chairman, the directive that you, in co-sponsoring Mr. Schiff’s bill, have made on the “inherent reasonableness” section we think really highlights the importance of doing something in this area.

Second, Medicare really can’t take advantage of its marketplace share in getting the discounts that they could rightly deserve through a competitive bidding process. At the current time, Medicare cannot contract with specific providers to provide specific items, in specific numbers, in specific geographical areas, to get a price that Medicare would like to be paying here.

Frankly, people that we talk with all the time just can't understand why the biggest payer of health care in the country can't use its market share to really effect the kinds of prices that other providers of care can. The Department of Veterans Affairs can. Every hospital in this country can. Insurance companies can. State Medicaid agencies can use their market share to competitively bid for prices, but Medicare cannot.

The third area really deals with its coverage policy. Medicare really can't move quickly to alter its coverage when it identifies a particular item that it believes is either open to abuse or is not effective for the beneficiary.

Last, regarding some of the abuses that we have found, particularly in nursing homes with incontinence supplies, wound care supplies, et cetera, if these items were bundled up into the daily nursing home rate, it would remove some of the opportunity for fraud. At the current time, after Medicare pays for the daily rate for a nursing home, it pays extra for the medical equipment that is provided directly to the individuals.

With that sort of background, I would like to now move into some of the equipment that we have been looking at over the years and bring to your attention some of the problems that we have found with it. My assistant, Teresa Revanna, is going to be pointing to some of the pieces of equipment as we get to it. Let me mention at the outset that some of these pieces of equipment are meant to be representative of the kinds of equipment that are out there and may or may not have been the ones that were actually involved in the individual cases.

I really first have to thank the Rayburn Health Unit for supplying this hospital bed. I would mention, though, that this bed is not the bed that we looked at when we did our study. We were looking at electric beds, and this one is not, but it will suffice, I think, for what I'm going to be talking about.

Medicare does pay for the home use of hospital beds when the positioning of the body is important in the recovery process, and it cannot be achieved through use of a normal bed. In 1994, Medicare allowed \$258 million for home use of hospital beds. We identified, in our study, that the wholesale price of those beds was about \$1,000, but over the useful life cycle of that bed, a supplier can actually bill for seven times that, \$7,000.

Orthotic body jackets are customized, rigid devices intended to hold the patient mobile who is recovering from a muscular or spinal problem. These can be purchased for up to \$1,200. Medicare payments captured our attention when they leaped 8,200 percent from 1990 to 1992.

Mr. SHAYS. Could you just explain when you say that piece of plastic costs how much?

Mr. MANGANO. Up to \$1,200. Medicare will allow up to \$1,200. It is customized. It is form-fitted to the individual.

As I was indicating, this item increased its allowable expenses in Medicare by 8,200 percent in just 3 years. It went from \$217,000 nationwide up to \$18 million. So that caught our attention, and we got involved in it. In our review of these, we found that about 95 percent of the devices that were actually being provided were not eligible to be reimbursed by Medicare.

What we found was that people who were billing for orthotic body jackets were actually providing seat pads and pads for wheelchairs, basically to restrain people in a wheelchair who may be in a nursing home environment.

Enteral nutrition therapy is nutrition that is provided for persons who have digestive tract problems and their digestive tract really can't absorb the kinds of foods that you would take normally through the mouth. In 1994, Medicare paid \$330 million for these nutritional items, mostly provided in nursing homes.

What we found here was that other payers of this nutrition were negotiating contracts with the suppliers. The discounts they were getting, if applied to Medicare, would have saved Medicare at least 17 percent to 48 percent of the cost of these devices. Further, if we considered these as a food product in a nursing home, we would save substantially more, up to \$170 million a year, because it really is food.

Home glucose monitors are portable devices to help measure a person's blood sugar. Those persons with diabetes use it to track their blood sugar levels. We were surprised when we found that we could go to a local drug store and purchase these for \$50, and yet the Medicare fee schedule allowed between \$144 and \$211 for these products. Medicare, to their credit, agreed immediately with us and began the rulemaking process to do this, but it took 2 years to do it. The price was eventually reduced to \$58, and they are now paying a more reasonable price.

Incontinence supplies are supplies available for individuals who have bladder control problems. Medicare allowances for this tripled in 3 years to \$230 million by 1993, despite a drop in the number of beneficiaries who were using them. What we found was, some suppliers were billing for devices they did not deliver, were charging for devices that were of far less quality; or they were not the items that should have been billed for.

As one example, instead of a female urinary collection pouch, which Medicare will pay \$7.38 for the supplier supplied a package of 33-cent diapers. Diapers are not in any way reimbursable by Medicare. About half of the claims in this area we questioned.

Lymphedema pumps are prescribed for patients diagnosed with a rare condition in which swelling develops after removal of the lymph nodes. These pumps help reduce the swelling in that. These pumps run between \$580 and over \$4,600. The scam that we were finding here was that they were providing devices at a lower quality but billing for the most expensive one. In one instance, we found a provider who actually overbilled \$690,000 for these devices.

Nebulizer drugs are drugs that are delivered through a nebulizer. This is a piece of equipment that administers prescription drugs of inhalation therapy. In 1994, Medicare allowed \$226 million. Medicare, we found, pays too much for these. If Medicare had paid exactly the same fee for three drugs in 17 States that Medicaid paid, they would have saved \$37 million.

Transcutaneous electronic nerve stimulators—we call them "TENS,"—are low-voltage electrical impulse generators. They are used for pain control, and they can be useful in about half the cases, but not all cases. We found, when we looked at the claims, that about one-third of the claims were either fraudulent or the

person did not have the trial period which would have identified whether the device would have been useful for them. That trial period is required.

Wound care suppliers are fillers or protective covers to treat openings in the body caused through surgery, wounds, ulcers, and other purposes. In 1993, Medicare allowed \$132 million for this. We looked at these and found about two-thirds of the wound care supplies that were supplied we would have questioned whether that bill should have been paid.

I will just highlight two egregious examples of that. We found one person who received 66,000 feet of 1-inch tape; that's 12½ miles in a 6-month period. Another person obtained 5 gallons of a wound filler, hydrogel. Both of these are absurd, and we developed cases out of these.

Let me conclude by saying the private sector third-party payers would not do business this way. They would go out of business this way. We have to do as much as we can to help Medicare become a prudent purchaser of services.

The last thing I want to say before I close is that regarding the two organizations who are going to be testifying after me, we have worked with them over the years, and we believe they are very highly ethical organizations. If all the members in the medical supply industry were as ethical as these organizations, at least some of the problems that I've talked about today would be resolved.

Thank you very much, Mr. Chairman. I will be happy to answer any of your questions.

[The prepared statement of Mr. Mangano follows:]

**Testimony of Michael Mangano
Principal Deputy Inspector General
Department of Health and Human Services**

Good morning. My name is Michael Mangano. I am the Principal Deputy Inspector General, U.S. Department of Health and Human Services. I am pleased to be here today to discuss issues relating to fraud, abuse, and waste related to Medicare reimbursement for medical equipment and supplies.

I want to begin my testimony by providing a few introductory remarks about the Office of Inspector General (OIG) and our unique role in combating fraud and abuse and improving the effectiveness and efficiency of the Medicare program. I then want to discuss some of the work we have done over the years related to medical equipment and supplies, to illustrate the range of both problems and solutions we've seen in this area.

Finally, I want to discuss some of the fundamental reforms that I think are warranted to make Medicare a more prudent purchaser of medical equipment and supplies. These reforms include expanding Medicare's ability to reduce inherently unreasonable prices, authorizing competitive bidding, allowing greater flexibility in making coverage decisions, and bundling certain nonprofessional services in nursing home rates.

INTRODUCTION

The OIG was created by law to protect the integrity of HHS programs and to promoting their economy, efficiency, and effectiveness. The OIG meets this challenge through a comprehensive program of audits, program evaluations, and investigations. Our role is to detect and prevent fraud and abuse and to ensure that beneficiaries receive high quality, necessary services, at appropriate payment levels.

The Medicare program is administered by the Health Care Financing Administration (HCFA). Medicare Part A covers hospital and other institutional care for approximately 37 million persons age 65 or older and for certain disabled persons. Medicare Part B covers most of the costs of medically necessary physician and other non-institutional services. At \$197 billion, FY 1996 Medicare expenditures will have increased about 9.4 percent over the FY 1995 level of \$180 billion. The HCFA contracts with private insurance companies to process Medicare claims including four specialty contractors that make payments for medical equipment and supplies paid under Part B.

MEDICARE VULNERABILITIES TO FRAUD

Vulnerabilities to fraud and abuse in the Medicare program have been well documented. Because of the huge sums of money being spent, the Medicare program will always attract some individuals or companies that dishonestly attempt to take advantage of loopholes or directly violate the law to enrich themselves at the expense of the taxpayer and the Medicare beneficiary.

Our office has been at the forefront of fighting fraud in the Medicare program. To leverage our effectiveness, we work with a variety of Federal and State entities to detect fraud and bring individuals and entities that have defrauded the program to justice. In Fiscal Year (FY) 1995, we were responsible for 620 successful criminal prosecutions and 1,563 administrative sanctions (civil monetary penalties or program exclusions) against individuals or entities that defrauded or abused the Department's programs and/or beneficiaries. Last year, the OIG also generated savings, fines, restitutions, penalties, and receivables of over \$10.2 billion (more than \$6.9 billion pertained to Medicare and Medicaid). This represents \$115 in savings for each Federal dollar invested in our office, or \$9.7 million in savings per OIG employee.

A year ago, we initiated a two-year partnership of Federal and State agencies working together to prevent and detect health care fraud in specific health care industries. This project, called Operation Restore Trust, targets five States which together account for approximately 40 percent of the nation's Medicare and Medicaid beneficiaries.

The impetus of the project was to more effectively use existing and expanded resources devoted to combat health care fraud and abuse. Operation Restore Trust represents one of the largest and most comprehensive efforts against health care fraud ever undertaken by the HHS Office of Inspector General (OIG), the Health Care Financing Administration (HCFA) and the Administration on Aging (AOA). The project uses the shared resources of the three primary HHS agencies as well as HCFA contractors and State and local resources to address fraud in three rapidly growing sectors of the health care industry: home health agencies, nursing facilities (including hospices) and medical equipment and supplies.

The OIG currently has more than 240 investigations underway that are related to Operation Restore Trust, including many joint ventures with the Department of Justice, the Federal Bureau of Investigation (FBI), the United States Postal Inspection Service, the Defense Criminal Investigative Service, the Railroad Retirement Board, and other law enforcement agencies.

While I can tell you that I think we have been successful in combating fraud, I can also tell you that I think there is much to be done. While we have found that fraud and abuse permeate all aspects of the program and all areas of the country, we believe that some program areas are more vulnerable than others. Vulnerabilities in medical equipment and supplies have been of particular concern to us.

MEDICAL EQUIPMENT, SUPPLIES AND RELATED ITEMS

Background

Medical equipment and supplies include several categories of items. Durable medical equipment (DME) are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, and other equipment that physicians prescribe for home use. Prosthetics and orthotics are devices that replace all or part of an body organ and include leg, arm, back, and neck braces as well as artificial legs, arms, and eyes. In addition, Medicare classifies enteral and parenteral nutrition therapy under the prosthetic device benefit. Medical supplies include catheter, ostomy, incontinence, and wound care supplies. Medicare Part B expenditures for all medical

equipment and supplies totaled more than \$5 billion in 1994. In addition, Medicare beneficiaries pay a 20 percent copayment for those items.

We have issued numerous reports on problems with this category of service and undertaken a large number of investigations. Some of the problems we have seen include:

- Filing claims for equipment that was never delivered.
- Billing for high cost equipment when lesser cost equipment was actually provided (upcoding).
- Billing for the component parts of a piece of equipment instead of the entire unit (unbundling).
- Delivering equipment that has no medical benefit or delivering medical equipment to beneficiaries who do not need it.
- Medicare reimbursement rates that are clearly excessive when compared to payments made by other payers or compared to the wholesale costs, or market discounts.

Program Reforms

Our work, as well as work by HCFA, the Congress, and the medical equipment industry have documented these types of deficiencies. As a result, the Congress and HCFA have taken a number of steps since the late 1980s to curb the abuses in the medical equipment and supplies area. In particular, two reforms deserve prominent mention:

- A fee schedule for DME was implemented in 1989 and the Omnibus Budget Reconciliation Act of 1990 established ceiling and floors to the DME fee schedules to make payments more uniform.
- In October 1993, HCFA began transferring claims processing for DME from 32 carriers located throughout the country to 4 regional carriers. As part of this process, point of sale rules were changed to require suppliers to bill the carrier that serves the jurisdiction where the beneficiary lives. In addition, HCFA required suppliers to apply for new provider numbers and meet certain minimum standards before numbers are issued.

Even with this corrective action, OIG work continues to document certain deficiencies in Medicare payment for medical equipment and supplies. It is clear that additional corrective action can be taken to reduce program vulnerabilities.

OIG Work

We often focus our attention on specific items of equipment or supplies when we see a significant increase in payments over a short period of time. In the absence of coverage or coding changes, or new medical information about proper use and application of technology, such increases have

often been an indication of fraud or inappropriate billings. Such increases have led us to examine claims for seat lift chairs, incontinence supplies, and wound care supplies. Also, when investigations indicate that there may be a systemic problem in a particular area such as body jackets, we initiate reviews to determine the extent of the problem. Finally, we attempt to look at broader payment issues related to medical equipment and supplies.

The following is a brief description of some of the work that we have done in this area over the past few years. A more complete description of this work can be found in appendix A of my testimony.

Enteral Nutrition Therapy -- We found that Medicare payments for enteral nutrients are excessive because nursing homes and even other third party payers are purchasing enteral nutrients at significantly lower prices than current Medicare levels.

Nebulizer Drugs -- We found that Medicare and its beneficiaries could have saved \$37 million if they had used the payment methodology used by Medicaid for nebulizer drugs.

Wound Care Supplies -- We found that questionable payments of wound care supplies may have accounted for as much as two-thirds of the \$98 million Medicare allowed for these items from June 1994 through February 1995.

Incontinence Supplies -- We found that questionable billing practices may account for almost half of the \$230 million allowed for incontinence supplies 1993. We have convictions for "carrier shopping," and billing for incontinence supplies that were never delivered.

Lymphedema Pumps -- Several of our investigations have shown that manufacturers and providers misrepresent the type of pump issued to Medicare beneficiaries in order to obtain significantly more reimbursement.

Oxygen Systems -- We found that Medicare, on the average, allowed 174 percent more than the Department of Veterans Affairs reimburses for oxygen concentrators. We also found significant variation in the services provided to beneficiaries associated with oxygen concentrators.

Orthotic Body Jackets -- We reported that 95 percent of claims paid by Medicare (\$14 million in 1992) were for non-legitimate devices. We have also obtained convictions of entities that billed Medicare for body jackets when they really provided seat pads.

Intraocular Lenses -- We found that ambulatory surgical centers were paying about \$126 for intraocular lenses while the Medicare reimbursement was \$200.

Total Parenteral Nutrition (TPN) -- We determined that Medicare overpaid \$69 million for TPN in 1991 (43 percent of total expenditures).

Hospital Beds -- We found that an electric hospital bed with a wholesale price of about \$1000 can generate about \$7000 in Medicare rental reimbursements to a supplier over the 5-year useful life of the bed.

Home Blood Glucose Monitors -- We found that while monitors could be purchased for \$50 at a drug or grocery store, Medicare fee schedules ranged from \$144 to \$211.

Transcutaneous Electronic Nerve Stimulators (TENS)-- We found that one-third of the claims for TENS should not have been paid because they were either possibly fraudulent or failed to meet Medicare coverage requirements for a trial period.

Seat-Lift Chairs -- Our analysis indicated that aggressive national marketing by suppliers had resulted in many beneficiaries initiating the request for the chairs. In 1989, Congress limited Medicare reimbursement to seat-lift mechanisms only and expenditures for seat-lift chairs and mechanisms dropped from \$122 million in 1988 to \$14 million in 1991.

In addition to our audits, and evaluations, we have aggressively pursued individuals and entities who have defrauded our programs in this area. Between 1990 and 1995, our investigations led to 145 successful criminal prosecutions of DME suppliers or their employees. During the same period, we imposed 35 civil money penalties (totaling more than \$43 million) and excluded 284 DME companies or their employees from the Medicare and Medicaid programs. Some examples of these concluded cases appear in Appendix B of my testimony to illustrate the types of schemes we have uncovered.

LESSONS AND CORRECTIVE ACTION

What conclusions do we draw from these experiences?

First, medical equipment and supplies is clearly an area which requires our attention, and is susceptible to fraud and abuse. This is probably the result of a combination of factors: high profit margins, ease of entry into the marketplace, and until regionalization of claims processing and fee schedules, a real looseness in how Medicare paid claims.

Second, although much progress has been made in this area over the years, more remains to be done. The accomplishments have been the result of a concerted effort on the part of our office, HCFA, the Congress, Medicare contractors, and industry representatives.

Third, there are some things Congress can do to improve the Medicare program, like stepping in to legislate specific reductions in prices (such as TENS) or coverage decisions (like limiting Medicare payment to the seat-lift mechanism). Other statutory improvements can be made to allow greater program flexibility and to close loopholes in the law. HCFA can promulgate rule-makings to adjust prices to reflect market conditions (as they did with the glucose monitors), promulgate more appropriate supplier standards, and continue to improve coding of equipment and services. Our office and industry representatives can continue to highlight deficiencies and make constructive suggestions about how to eliminate them.

But most important, if you were to take away only one thing from my testimony today, I would wish that it would be this: the Medicare program is far too limited in how it can act and how quickly it can act. I'd like to suggest to you that significant improvement could be made in protecting the Medicare trust funds and our Federal and State investment in Medicaid if program managers could move quickly to address problems such as these when they are identified. Too frequently, I see one kind of abuse or inefficiency identified, discussed, and addressed over time, only to see it replaced by a new variation and a new scheme, or perhaps simply a new market condition. The following are some specific actions which I believe can be taken to improve the situation:

Inherently Unreasonable Payment Levels

In a competitive health care market, prices will change. In general, even when the OIG or HCFA identifies a particular piece of equipment as significantly overpriced (i.e., as "inherently unreasonable"), the Department or carriers cannot adjust reimbursement levels without going through the regulatory process that was used to reduce payment level for glucose monitors. The regulatory process is a resource-intensive and time-consuming process. It can take from 2 to 4 years. The only other alternative is for the Congress to legislatively reduce the payment amount. We recommend that the Congress enact legislation which would allow HCFA to apply "inherent reasonableness" in setting reimbursement amounts (this would allow downward adjustments). The Department actually had this authority prior to 1987. Enactment of this provision would allow HCFA to take more timely action in setting appropriate payment levels.

Competitive Bidding

HCFA does not have the statutory authority which would allow it to take advantage of its marketplace position to obtain discounts through competitive bidding. While competitive bidding is not appropriate for every aspect of the Medicare program, we believe that it can be used effectively in many areas. Competitive bidding would allow HCFA to contract with specific providers to deliver a fixed number of items and services to Medicare beneficiaries in specific geographic locations at a fixed price.

Most people I talk to simply cannot understand why Medicare is not allowed to do what other businesses can do -- take advantage of its market position to reduce expenses. The Department of Veterans Affairs can do this for its health care system; States can do it for Medicaid; commercial health maintenance organizations can do it; every hospital in the country can do it. But Medicare, which outspends them all, cannot use its marketplace leverage to obtain the best prices for the products and services delivered to its beneficiaries.

HCFA currently has a competitive bid demonstration project underway. We are pleased that HCFA is using its current legislative authority in this limited way. However, we believe that the Congress should expand HCFA authority to use competitive bidding even prior to the conclusion of the HCFA project.

Coverage Policy

HCFA does not have the authority to quickly and administratively alter coverage policy when its past policies and definitions prove open to abuse or when it is determined that an item or service is not medically effective. When HCFA makes a decision to cover a procedure or item nationally (as opposed to a specific contractor making a decision to cover an item locally), HCFA has to go through the rule-making process to withdraw that coverage.

Seat lift chairs provide a compelling example. When we looked into this, we believed that this piece of equipment was not really medically necessary. It was, in effect, a comfortable lounge chair with a seat-lift mechanism that was being aggressively marketed at Medicare's expense. Most beneficiaries who received them did not need them for their stated purpose. We found a simple, inexpensive seat-lift mechanism would work just as well.

When we called this to HCFA's attention, HCFA began the arduous, time-consuming regulatory process needed to determine whether to withdraw coverage of this item. Meanwhile, by 1988, Medicare reimbursements had risen to \$122 million. Fortunately, the Congress stepped in with legislation in 1989 to limit coverage to the seat-lift mechanism only. Medicare payments dropped to \$14 million in 1991. If Congress had not intervened, Medicare payments would have continued above \$100 million for at least 1 additional year, and maybe more.

The Congress should not have to make routine coverage decisions for the Medicare program. And HCFA should not be prevented from doing so either—especially in the face of an obvious scheme to abuse the program. We recognize the need for due process and public input on important coverage decisions. However, HCFA ought to be able to take interim action to withdraw or modify coverage while the rule-making process is carried out.

Consolidated Billing or "Bundling"

We believe that a long-term solution to some of the abuses we have found associated with wound care and incontinence supplies is to institute a statutory bundling of certain nonprofessional services provided in nursing facilities. When our parents, other relatives, or friends are placed in a nursing home, we expect that the daily rate that is paid for them covers normal and customary expenses. We would be surprised, for example, to be billed for nutrition services, incontinence supplies, or routine wound care. Yet, Medicare and Medicaid are sometimes billed for these and similar items, above and beyond the daily rate. Savings could result if these items were purchased by the nursing facility, acting as a prudent purchaser and taking advantage of discounts, rather than being billed to Part B and reimbursed under fee schedules. We also note that when services are billed under Part B, the beneficiary is liable for coinsurance and deductibles.

As a general matter, we are concerned about the provision of services and equipment to beneficiaries in nursing facilities because there are a multiplicity of providers who provide services to the beneficiaries. No single individual or institution is truly held responsible for managing the beneficiary's care and ensuring that only needed services are delivered to the patient. Indeed, many of the incentives run in quite the opposite direction.

CONCLUSION

It is worth noting, in this era of reinvention and reengineering, that private sector third-party payers do not operate under the constraints that the Medicare program operates under. They are not bound by the prescriptive nature of the Social Security Act or the Administrative Procedures Act. While some of these requirements may serve useful purposes despite the limits they place on the Medicare program, some may prevent program managers from taking appropriate action to improve program operations.

I appreciate the opportunity to appear before you today and to share with you some of our concerns and work we have done. I would be happy to respond to any questions you might have.

APPENDIX A

OIG AUDITS AND EVALUATIONS RELATED
TO MEDICAL EQUIPMENT AND SUPPLIES**Enteral Nutrition Therapy**

Enteral nutrition therapy provides nourishment to the digestive tract of a patient who cannot eat normally, generally due to disease or malfunction of the digestive tract. In 1994, Medicare allowed over \$680 million for enteral nutrients and related supplies (infusion equipment, etc). For enteral nutrients alone, Medicare allowed over \$330 million. The majority of patients receiving enteral nutrition covered under Medicare reside in nursing homes, with a smaller number receiving therapy at home.

In a February 1996 report, we reported that Medicare payments for enteral nutrients are excessive, because reimbursement rates are set too high. Data from several sources confirm that nursing homes can purchase enteral nutrients at significantly lower prices than current Medicare levels. For example, Medicare reimburses Category I nutrients (the simplest and most widely used formulas) at \$0.61 per unit, while average costs to a nursing home are approximately \$0.43 per unit. While many nursing homes are able to obtain discounts through buying groups or other relationships, we found that many report costs at or near Medicare reimbursement. Additionally, Medicare's current policy does not recognize enteral nutrients as food. If recognized as food, payment for enteral nutrients would be made as part of a facility payment rather than separately billed to Part B and Medicare would save approximately \$170 million annually.

In a separate report, we found that Medicare's current reimbursement policy fails to take advantage of competitive acquisition strategies employed by other purchasers. In comparing Medicare reimbursement to other health care payers, we found that other payers who utilized negotiated contracts with suppliers or other discounts, reimbursed from 17 to 48 percent less than Medicare. We estimated that Medicare could save \$19 million annually.

In a May 1995 survey of Medicare risk-contracted and private HMOs, facilities from the Department of Veterans Affairs, Medicaid State agencies, commercial payers and Blue Cross Blue Shield Associations, we found that most routinely cover enteral nutrition therapy. Compared to other payers, Medicare's coverage requirements are similar in some areas and more restrictive in others.

Nebulizer Drugs

Medicare covers prescription drugs under Part B for certain medical disorders, such as end-stage renal disease and cancer, and when necessary for the effective use of DME. Reimbursement is based on the lower of an estimated acquisition cost or a national average wholesale price (AWP). A nebulizer is a type of DME used to deliver medication by inhalation.

In February 1996, we released a report comparing 1994 Medicare allowances for three nebulizer drugs in 17 States to payments under the Medicaid program. Payment for drugs under the Medicaid program varies among the States, but generally includes use of discounted wholesale price, as well as the federally mandated manufacturers' rebate program (OBRA '90). We found that Medicare and its beneficiaries could have saved \$37 million if they had used the payment mechanisms available to Medicaid (reduced AWP plus a manufacturers' rebate).

Wound Care Supplies

Wound care supplies are fillers or protective covers that treat openings on the body caused by surgical procedures, wounds, ulcers, or burns. Wound covers are flat dressing pads. Wound fillers are dressings placed into open wounds to eliminate dead space, absorb exudate, or maintain a moist wound surface. Medicare Part B allowances for wound care supplies were as low as \$50 million in 1992 and peaked in 1993 at \$132 million, an increase of 164 percent. The number of beneficiaries that annually received these supplies ranged from 86,600 in 1993 to as high as 273,300 in 1991.

In an October 1995 report, we found that questionable payments of wound care supplies may account for as much as two-thirds of the \$98 million in Medicare allowances from June 1994 through February 1995.¹ In the more egregious cases, one beneficiary was charged \$5,290 for tape over a 6-month period, almost \$5,000 of which appears excessive. Medicare paid for, but the beneficiary probably did not receive, 66,000 feet or 12.5 miles of one-inch tape. Another beneficiary was charged with \$11,880 in hydrogel wound filler, \$11,533 of which may be unnecessary. This beneficiary's record showed payments for 120 units of one-ounce hydrogel wound filler each month for 6 consecutive months, or over 5 gallons.

We also assessed the marketing of wound care supplies in an October 1995 report and found that nursing homes and physicians generally determine which patients need supplies, but some suppliers determine the amount provided. Of most concern, we found that 13 percent of nursing homes have been offered inducements in exchange for allowing suppliers to provide wound care products to patients in their facility. Finally, 11 percent of beneficiaries reported that they used either none or only some of the wound care supplies they received. In almost half of nursing facilities, supplies are not identified or marked for use by a specific patient when delivered.

Incontinence Supplies

Incontinence supplies are supplies used for individuals who have bladder or bowel control problems. Medicare Part B covers supplies for urinary incontinence. Medicare allowances for incontinence supplies more than doubled in 3 years (\$88 million in 1990 to \$230 million in 1993) despite a drop in the number of beneficiaries using these supplies (312,000 to 293,000).

In a December 1994 study, we found that questionable billing practices may account for almost half of incontinence allowances in 1993. Approximately \$88 million was allowed for accessories that were not billed along with a catheter, indicating that coverage guidelines were not met. Another \$19 million in allowances were made for beneficiaries who appeared to receive more supplies than necessary. Together these questionable allowances amounted to \$107 million in 1993. If left unchecked, the cost to Medicare will be \$535 million over the next 5 years.

In a second December 1994 study, information obtained from nursing facilities and beneficiaries indicates that some suppliers engage in questionable marketing practices. Also, beneficiaries may be receiving unnecessary or noncovered supplies and some suppliers present nursing homes with false or misleading information about Medicare coverage for these items.

We concluded this by applying the proposed DME Regional Carrier draft guidelines to a sample of paid claims and by labeling those not meeting the guidelines as questionable. It is important to note that the guidelines were not in effect during the period of our review -- they became effective October 1, 1995.

In a third study released in November 1995 on Medicaid payments for incontinence supplies, we found that half of the States in our sample had encountered improper billings for incontinence supplies under the Medicaid program. In California, improper payments exceeded \$100 million. Other States experienced problems, but to a lesser degree. We also noted that State Medicaid agencies were unaware that certain copayments and deductibles paid on behalf of beneficiaries dually eligible for Medicare and Medicaid were inappropriate. Currently, Medicare does not require the carriers to notify Medicaid State agencies of improper Medicare payments made on behalf of Medicaid beneficiaries.

Oxygen Systems

Designed primarily for home use, oxygen concentrators provide long-term, life-sustaining supplemental therapy for patients with inhibited pulmonary function. Medicare allowances for oxygen concentrator rentals last year exceeded \$1.1 billion.

Our work has led us to conclude that Medicare payments for oxygen concentrators are excessive. We have examined how the U.S. Department of Veterans Affairs (VA) and other non-Medicare payers obtain and pay for oxygen systems and their reimbursement levels. In two prior reports (released in 1987 and 1991), we noted that the VA's contract prices were considerably lower than those paid by Medicare. In fact, our 1991 report found that Medicare, on the average, allowed 174 percent more than the VA reimburses for oxygen concentrators.

We began work to provide an up-to-date, detailed pricing comparison between the VA and Medicare in 1994. Late that year, the HCFA Administrator committed to a full HCFA review of oxygen pricing. As a result, we provided HCFA staff with our work papers and turned our attention elsewhere. The HCFA has been analyzing oxygen payment levels and building on our work in order to determine a fair reimbursement level. The reconciliation bill passed by the Congress contained a provision to phase in a 30 percent reduction in Medicare reimbursement for oxygen.

In this debate over pricing, it is important not to lose sight of the issue of services. Medicare patients receiving oxygen therapy typically require services such as equipment monitoring and maintenance, emergency service, and patient instruction and assessment. These support services are critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides. In a November 1994 report, we found significant variation in the services provided to beneficiaries. Eight percent of the sampled beneficiaries did not receive any equipment services and nearly half received no patient services. We concluded that HCFA policies contribute to the variation in support services because they fail to delineate specific service requirements for suppliers.

Orthotic Body Jackets

Orthotic body jackets are customized, rigid devices intended to hold patients immobile and treat patients with muscular and spinal conditions. Medicare payments for orthotic body jackets increased by over 8,200 percent from 1990 to 1992 (from \$217,000 to \$18 million), causing us to examine this phenomenon

In June 1994, we reported that 95 percent of claims paid by Medicare (\$14 million in 1992) were for non-legitimate devices. These non-legitimate devices are more properly categorized as seat cushions rather than body jackets. In addition, in March 1994 we reported that suppliers, rather than physicians, initiated orders for the non-legitimate body jackets, and that physicians provided limited controls for preventing the sale of non-legitimate devices. Corrective action taken by HCFA resulted in payments decreasing to \$7 million in 1994. In 1995, such payments were \$5.6 million.

Intraocular Lenses

Cataract extraction with an intraocular lens (IOL) insertion is the most frequently performed procedure paid by Medicare and accounts for approximately 6 to 8 percent of the Medicare outpatient budget. In 1991, Medicare paid for an estimated 1.14 million IOLs, about one-third of which were implanted in ambulatory surgical centers (ASCs). Prior OIG reports issued in 1986 and 1990 concluded that Medicare reimbursement for IOLs were also excessive, resulting in congressional and administrative action to reduce reimbursement to \$200 (saving about \$100 million annually). We had also reported in 1990 that the average cost of an IOL in Indian Health Service hospitals was \$155 and the average cost in Canadian hospitals was \$110.

As marketplace forces continued to reduce IOL prices, we reexamined Medicare payment levels. A March 1994 report issued by our office found that ASCs were paying about \$126 for each IOL, while the Medicare reimbursement was \$200. We also found that the ability of a purchaser to secure a low price did not depend on the type of lens technology purchased, volume of lenses purchased, or the size of the institution purchasing the lens.

In response to preliminary findings from our work, the Congress acted in the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66) to reduce the reimbursement levels to a flat \$150 for IOLs furnished in ASCs. This provision resulted in savings of \$18 million annually.

Total Parenteral Nutrition

Total parenteral nutrition (TPN) is a "high tech" means of feeding patients who do not have a functioning intestinal tract. In 1991, Medicare paid a total of \$162 million for this service.

In a May 1993 report, we determined that Medicare overpaid \$69 million for TPN in 1991 (43 percent of total expenditures). More than half the patients in our sample had end stage renal disease (ESRD) and received parenteral nutrition as a supplement three times a week. HCFA guidelines do not allow coverage of TPN when it is provided as a supplement.

Also in May 1993, we conducted a review of payments for referrals of parenteral nutrition patients and found that some suppliers are paying ESRD facilities to administer their parenteral nutrients.

Hospital Beds

Under the DME benefit, Medicare allows for the reimbursement of a hospital bed used by a Medicare beneficiary in the home when the bed is prescribed by a physician. To qualify for Medicare payments for a hospital bed, a beneficiary must have a condition that requires positioning of the body (e.g., to alleviate pain, promote body alignment, prevent contracture, or avoid respiratory infections) in ways not feasible in an ordinary bed.

In May 1993, we issued a report which addressed Medicare reimbursement for hospital beds and found that HCFA's current reimbursement methodology does not adequately reflect the useful life of the equipment. This results in excessive payments to suppliers. At the time of our study, an electric hospital bed could be acquired by a supplier for an average of about \$1000. Such beds have a useful life of approximately 5 years. Medicare pays for the use of the bed on a monthly basis and a typical hospital bed can be rented 7.5 to 10 times over its useful life, resulting in total Medicare payments of around \$7000 for the bed. The OIG recommended that HCFA reimbursement reflect the 5-year useful life and the many times the bed can be rented. One recommendation was to lower the monthly rental rates and extend the rental reimbursement

period from the present maximum of 15 months to 60 months. The HCFA did not agree with our recommendations.

Home Blood Glucose Monitors

A home blood glucose monitor is a portable device that measures a person's blood sugar level. Used on a daily basis, these monitors allow diabetic patients to detect and treat fluctuations in blood sugar levels.

In December 1992, we reported that Medicare fee schedules for blood glucose monitors were excessive. While the monitors could be purchased for \$50 at a drug or grocery store, we found that Medicare fee schedules nationwide ranged from \$144 to \$211. In addition, we actually found that beneficiaries could get rebates on the purchases of monitors that equaled the cost of the monitor, resulting in no cost to the beneficiary. At the same time, because it is difficult to identify rebates paid to customers, Medicare paid the full amount under the fee schedule. We noted that the anti-kickback statute prohibits rebates when the discount is not accurately reported to Medicare or Medicaid.

In response to our report, HCFA issued a final rule in January 1995 which established a flat payment amount of \$58.71 for blood glucose monitors. HCFA estimates that enactment of this rule resulted in savings of \$5 million annually. It is our understanding that this was the first time that HCFA used the rule-making process to adjust payment levels for DME.

Transcutaneous Electronic Nerve Stimulators

A transcutaneous electronic nerve stimulator (TENS) is a low-voltage electrical impulse generator used as a non-narcotic pain control device. It does not work well in all cases, but may give symptomatic relief of pain. Medicare reimbursement for TENS increased from \$15 million in 1985 to \$38 million in 1987.

In a July 1989 review, we found that one-third of the claims for TENS should not have been paid because they were either possibly fraudulent or failed to meet Medicare coverage requirements for a trial period.

Heightened awareness of abuses associated with this piece of equipment led the Congress to reduce reimbursement rates (15 percent in 1989 and another 15 percent in 1990) and take other action (i.e., putting on the list of "abused" items). As a result, we saw a significant decrease in program expenditures for these items. In 1993, the Congress further reduced TENS reimbursement by 30 percent.

Seat-Lift Chairs

Seat-lift chairs are mechanized chairs that assist a person in standing up and sitting down. Expenditures for these chairs almost doubled from 1984 to 1985, from \$33 million to \$63 million.

Our February 1989 analysis indicated that aggressive national marketing by suppliers had resulted in many beneficiaries initiating the request for the chairs. Further, we determined that many of these beneficiaries did not need assistance in standing up and used the devices as pieces of furniture rather than medical equipment. As a result of our work, the Department began work on regulations to address the problem. While that activity was underway, we testified before Congress and a legislative solution was implemented. The Omnibus Budget Reconciliation Act of 1989 limited Medicare reimbursement to seat-lift mechanisms only.

As a result of this action, expenditures for seat-lift chairs and mechanisms dropped from \$122 million in 1988 to \$42 million in 1990 and \$14 million in 1991. Since payments are only made for the seat-lift mechanism and not for the chair itself, suppliers are no longer reimbursed when they provide a chair that serves as a piece of furniture.

APPENDIX B

SELECTED CASE EXAMPLES
RELATED TO MEDICAL EQUIPMENT AND SUPPLIES**Incontinence Supplies**

Not long ago we had the first prosecutive action under our national incontinence care investigations project targeting DME companies which supply incontinence care, urological and orthotic items to patients in nursing facilities and long-term care facilities. Geoffrey Bradley, former employee of a Tennessee-based DME company, pled guilty in Massachusetts to conspiracy to defraud Medicare in a multi-million-dollar fraud scheme. Bradley's company, Providers, Inc., billed for items sold as far away as California and Florida. It engaged in "carrier shopping," determining the States in which carriers paid the highest Medicare reimbursement and using shell offices or mail drops to create the illusion that its supplies were sold in those States. It also billed for supplies never provided, including supplies for deceased nursing facility patients. The company has filed millions of dollars in fraudulent claims across the country, including \$4.4 million in Massachusetts alone. Subsequent to Bradley's plea, company owner/President Gary Lakins and former senior managers, Karen DeRosa, Randy Jenkins and Tammy Simpson, all of Tennessee, were indicted and arrested.

Sharon Harris, former employee of the manager of Lincoln Care Center, was sentenced in California to 18 months in jail and fined \$12,500 for her part in a multi-million dollar Medicare fraud scheme. Harris and another employee pled guilty to assisting Frank Aiello with submitting claims for catheters never provided to the patients in the skilled nursing facility. The other employee was sentenced earlier, as were two carrier employees who altered records for Aiello. Aiello was recently sentenced to 11 years and 3 months imprisonment and ordered to pay fines, restitution and special assessments of more than \$3.5 million.

In Ohio 24 agents conducted searches at a DME company and a billing service owned by William Harris. The DME company supplied adult diapers to nursing home patients in Illinois, Florida, California and Puerto Rico, as well as Ohio, which were billed to Medicare as female urinary collection devices. Damage to the Medicare program has thus far been identified as \$16 million. More than \$1 million in damages resulted from reimbursement of supplies to nursing homes in Illinois.

Lymphedema Pumps

Lymphedema pumps are prescribed for patients diagnosed with chronic intractable lymphedema, a rare medical condition in which swelling develops after the removal of the lymph nodes. The pumps are effective in reducing the swelling. The Medicare program reimburses for lymphedema pumps under three different codes: E0650, E0651, and E0652. The least sophisticated and least expensive pumps are coded E0650 and E0651, which are reimbursed by Medicare at \$580 and \$686, respectively. The most sophisticated and expensive pumps are coded E0652 and are reimbursed by Medicare at over \$4,600. The Medicare program requires that a certificate of medical necessity be signed by a physician and accompany a claim for reimbursement. There are certain contraindications for using a lymphedema pump. Because of the high reimbursement, the amount of potential fraud can rapidly reach \$100,000 with only 20 or 30 claims.

Several of our investigations have shown that manufacturers and providers misrepresent the type of pump issued to Medicare beneficiaries in order to obtain significantly more reimbursement. The regions in which investigations are ongoing or have been completed reported that the lymphedema pump is a "big ticket"

item with a large potential for fraud. Since lymphedema pumps are used to move fluid from extremities to reduce swelling, they should not be used for patients with congestive heart failure, and continued use could be detrimental to the patient's health. Thus, both the medical necessity and usage of the lymphedema pumps can be questionable. In some cases lymphedema pumps are being provided to patients who have only regular edema. One provider billed Medicare \$4,500 for each gradient pressure pump but supplied the patient with non-gradient pressure pumps, which were reimbursed at approximately \$600. Another provider had an arrangement with a family nurse practitioner in a rural health clinic whereby all Medicare patients were called to the clinic and a lymphedema pump was given to each beneficiary.

National Medical Systems, Inc. — a Maryland DME company — agreed to pay \$1.5 million to resolve liabilities under the Civil Monetary Penalties Law. Over a year's time the company submitted claims for lymphedema pumps under a code for which the pumps did not meet specifications. As a result, the company was overpaid approximately \$690,000. As part of the settlement it was required to enter into a compliance plan to prevent improper billing. The case was the fourth settled in a national project focusing on manufacturers and retailers of lymphedema pumps.

The owner of Global Medical Systems, a DME supplier, pled guilty in New Jersey to defrauding the Medicare program. Kevin Dyeovich had submitted claims for lymphedema pumps at \$4,000 each, when he actually furnished pumps costing about \$800 each, to carriers in California and Maryland he was certain would pay. On several occasions, he billed and was paid by more than one carrier for the same service. Dyeovich's plea covers a 1-year period during which he defrauded Medicare of about \$320,000. A civil settlement is being negotiated.

Bernice Tambascia, owner of the largest Medicare supplier of lymphedema pumps in New Jersey, was convicted for Medicare fraud and obstruction of justice. In a scheme involving beneficiaries in Florida and New Jersey, Tambascia billed Medicare for pumps not medically necessary and falsely claimed a cheaper pump had been rented before billing for the \$4,000 pump. She was overpaid more than \$200,000.

A podiatrist who served as middle man for a DME company was arrested in New York. Barry Feldman offered and paid kickbacks to a cooperating physician for names and claim numbers for Medicare beneficiaries and the physician's identification number. Feldman received \$300 for each referral to the DME company and paid the physician \$200. Each patient received a lymphedema pump regardless of medical necessity, and Medicare was billed for a \$4,800 piece of equipment.

Orthotic Body Jackets

In Texas, our investigation into orthotic body jacket fraud led to DME company owner Jimmy Mathis, his partner Gary Blakley and company manager Larry Lane being ordered to make restitution, jointly and severally, of \$386,500 for their part in a false billings and kickbacks scheme. They had billed Medicare for body jackets when they really provided seat pads. The seat pads were manufactured in Mexico for \$50 each, but Medicare was billed \$1,200. Over a 2-year period the company billed Medicare more than \$1.6 million. In addition, nursing home owner George Renfro had accepted bribes from Mathis for permitting his company to supply ostomy and feeder supplies to a nursing home Renfro and his wife owned. Mathis purchased \$500,000 in life insurance policies for the Renfros in exchange for being allowed to supply the nursing home. Mathis was sentenced to 33 months in prison and 3 years probation, Blakley and Lane to 150 and 180 days home detention and probation, and Renfro to 180 days home detention and 5 years probation. The OIG has excluded Mr. Mathis for a minimum of 12 years and Mr. Blakley and Mr. Lane for a minimum of 10 years each from being able to participate in Medicare and any State health care program. Action is currently underway to exclude Mr. Renfro.

Support Products, Inc., a DME company in Texas, was sentenced to 1 year of probation for filing false Medicaid claims for services not rendered. As part of the plea agreement the company was also ordered to pay restitution of \$450,000. The DME company supplied wheel chair pads to nursing home patients and then fraudulently billed Medicare under the code for a lumbar sacral support system, also known as a "body jacket." Earlier, J. Michael Pruitt, former owner of the DME company, pled guilty to mail fraud.

Prosthetist William Lee, who owned a California DME company, was sentenced to 7 months in prison and 3 years supervised release for Medicare fraud. Lee submitted 44 claims for orthotic bilateral contracture devices, purportedly for nursing facility residents, which he never provided. After an investigation was begun and the carrier began withholding reimbursement, he submitted claims under the provider number of a friend, set up a second business in a friend's name, and submitted more false Medicare claims for prosthetic and orthotic devices. On the basis of an earlier plea agreement he is to pay the Government \$400,000. As a result of this conviction, the OIG excluded Mr. Lee from Medicare and any State health care program for a minimum of 25 years.

Other Cases of Interest

Harry Ullrich, owner of record of Infinite Medical Supplies, a New York DME company, was sentenced for fraudulently billing Medicare \$2.36 million over an 18-month period. Infinite was part of Universal Medical Supplies and participated in a fraud scheme that cost Medicare more than \$6 million. The scheme involved at least four doctors, eight salespersons and three company principals who engaged in false statements, kickbacks and conspiracy by billing Medicare for reimbursable items such as hospital beds and wheelchairs which beneficiaries never received. Ullrich was sentenced to 37 months in prison and 2 years probation. Earlier Ullrich agreed to forfeit \$736,500 in cash and property already seized, in settlement of a civil suit for overcharging Medicare. He also must turn over an additional \$112,000. The OIG is presently taking the necessary steps to exclude Mr. Ullrich from Medicare and any State health care programs.

William Drumheller, owner of a now-bankrupt DME company in Illinois, was sentenced to 5 months imprisonment and 5 months home confinement for defrauding Medicare of close to \$61,000 over a 1-year period. Drumheller obtained names and health insurance claim numbers of nursing facility patients. He then forged physicians' signatures on medical necessity forms and filed claims for equipment, including beds, wheelchairs and mattresses, which he never provided. The investigation of Drumheller uncovered a sordid past that included a criminal conviction for murder. Former employees interviewed recalled episodes of sexual misconduct and violence. During the investigation Drumheller filed for bankruptcy and made false statements, but the trustee decided not to prosecute. Action to exclude Mr. Drumheller from program participation is presently being undertaken.

In Pennsylvania, John Cocivera and six DME companies he owned were found guilty of mail fraud and submitting false Medicare claims. Cocivera's companies contacted Medicare beneficiaries by telephone and solicited their acceptance of unneeded DME. For example, many beneficiaries who received special bed pads stated they were ambulatory and did not feel they were susceptible to decubitus ulcers. Others said they never used any of the equipment received. Many beneficiaries' doctors said the DME was not medically necessary. A review of patient files showed them to have been altered, with information whited out or crossed out and changed, and much of the information was handwritten and entered with a pen other than that used in the doctor's signature. The estimated loss to the Government is \$2.5 million. Cocivera was sentenced to 78 months in prison and his companies were assessed \$78,000.

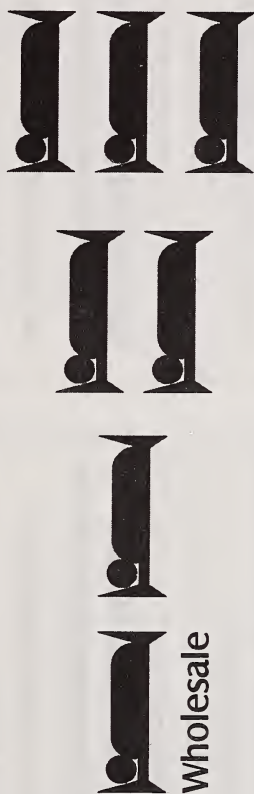
Bella Yemdin, a recruiter of Medicare beneficiaries for Universal Medical Supply, a DME company, pled guilty in New York to conspiracy. Four doctors, seven other recruiters and three company principals have

been charged in a scheme in which the recruiters were paid for engaging beneficiaries and the doctors signed medical necessity forms for unneeded equipment for beneficiaries they never saw. The beneficiaries received items such as microwaves, air conditioners and angora underwear, for participating, and the company billed Medicare for items such as hospital beds and wheelchairs. The case involved \$13 million in Medicare claims. Superseding indictments have been brought against three of the physicians and three of the recruiters, containing additional charges as well as the original ones of false statements, kickbacks and conspiracy.

As a result of a civil settlement, two Arkansas DME company owners, George Kirtley, Sr., and his wife, Ruth Kirtley, were permanently excluded from participation in Medicare and any other State health care programs. This settlement also required them to pay more than \$1.9 million to resolve the civil violations.

Manuel J. Aguirre, the director and stockholder of a Florida DME company, entered into a CMP agreement whereby he agreed to pay \$65,000 and be excluded from program participation to resolve the allegations regarding his payment of kickbacks.

7 to 1 Reimbursement for Electric Hospital Bed Rentals



In a single-State review, the OIG projected that an electric bed with a wholesale price of ~\$1000 could generate ~\$7000 in reimbursements over its 5-year useful life.

Orthotic Body Jacket

- Suppliers claim nonlegitimate devices like seat cushions.
- Allowances up 8,200%, 1990-92.
- 95% (\$14 million) of 1992 claims were for wrong item.

Home Blood Glucose Monitors

- Fee schedules too high.
- Cost about \$50.
- Medicare paid \$144-\$211.

Enteral Nutrients

- Disease or malfunction of digestive tract.
- \$330 million in 1994.
- Part A covers food.

Incontinence Supplies

- \$ doubled in 3 years to \$230 million in 1993.
- Covered device vs. diaper.
- Aggressive marketing.

Lymphedema Pumps

- Range ~\$580 - \$4,600.
- Higher item billed.
- One Supplier was overpaid \$690K.

TENS

- Transcutaneous Electronic Nerve Stimulators.
- 1987=\$38m. 1994=\$8m.
- Congress reduced rates.

Nebulizer Drugs

- Inhalation therapy.
- Medicare paid 37 million more than Medicaid on 3 drugs in 17 States.

Wound Care

- \$132 million in 1993.
- Two thirds of sampled claims were questionable.

Mr. SHAYS. Thank you. I'm going to call on Mr. Horn, but I just would like one of your staff, before I prepare to ask a question, on the \$690,000 rip-off, I would like to know specifically about the case. I would like to know what happened. If someone is not certain, if they would call up and get that information before my round of questioning comes.

Mr. MANGANO. OK.

Mr. SHAYS. That deals with which piece of equipment?

Mr. MANGANO. That was, I think, the orthotic body jacket.

Mr. SHAYS. OK.

Mr. MANGANO. I'm sorry, the lymphedema pump.

Mr. SHAYS. Right. If someone would be prepared to respond to that question when my turn comes. I will call on the other Members before I go.

Mr. Horn.

Mr. HORN. Thank you very much, Mr. Chairman.

I thank you for your testimony. Your examples confirm what I have long suspected, that it isn't simply waste, fraud, and abuse outside of Medicare, it's stupidity, administratively, within Medicare and Medicaid, in the health care financing group.

Now, when you look at this, is the reason they can't get a rule changed rapidly what the Congress wrote in the original law? I happen to have been on the drafting team, and I can't recall limiting them in 1965. Or is it under the Administrative Procedures Act, or is it just their own internal regulations? Where does Congress go to turn this around?

Mr. MANGANO. We think that another process outside of the rule-making process is needed here or some modification of the rule-making process. If we do follow the Administrative Procedures Act, for these particular products, the first thing that HCFA would have to do would be to do market surveys to find out what the prices were, and those can be time-consuming. Then they would have to develop a proposed rule.

The proposed rule, after it is developed and approved by the administration, the department, as well as the Office of Management and Budget, would then go out for public comment. Public comment could be several months or it could be a month. Once those comments are in, every comment has to be addressed. Then a final rule is published. Under the best of circumstances, in my 26 years in this department, 2 years is flying through the process.

What we believe is necessary is some modification to that. For example, if HCFA were able to issue, after they did a market survey, a tentative pricing change, and then go through the rest of the rulemaking process as they fully develop comments with the industry and others, and go through the rest of the rulemaking process, that would be a big help.

Mr. HORN. Yes. I must say, Mr. Chairman, I feel very strongly that we need to give this agency emergency power in order to get on top of this situation. To see these billions of dollars flowing out through their decisionmaking process and their inactivity—it has nothing to do with one administration over the other—this has been going on for years. We've got to clean up that process and streamline it.

You don't need to have the Census Bureau and everybody else go out and do a market survey. You just need to find out what the price structure is or have a filing of what is charged for these around the country. I just think we have to look at the real problem. The real problem is, they can't act in a reasonable time.

Mr. MANGANO. Right.

Mr. HORN. I think I would certainly ask our joint staffs to work on this and come up with a bill we can introduce and solve that problem.

Now, let's move to the market share bit. What is your feeling on that, as to looking at it from a market share standpoint? What experience has the Inspector General's Office had with this, and what have you concluded?

Mr. MANGANO. Almost every study that we do on a piece of equipment that we believe is overpriced, we will take a look at what other payers in the process are paying, whether it's the Veterans Administration, or the Office of Personnel Management, or the HMOs, or other payers. Everybody is paying less than Medicare.

Now, I'm sure there are some in which they are not paying more than others, but our experience has been that other payers, using competitive bidding processes or other measures, can get better rates. For some of the examples that I used today, on the nebulizer drugs, for example, we found other payers getting discounts that Medicare is not getting.

I will give you one example that I didn't talk about here that I think absolutely makes the case. About 5 years ago, we were looking at the most prevalent procedure that Medicare pays for, and that's cataract surgery. And the intraocular lens that is implanted, the synthetic lens, during the cataract surgery, is a device ambulatory surgical centers, who do about one-third of these procedures, were billing Medicare for \$350 for each of these lenses.

So we said, "Well, is that a good deal or is it a bad deal?" We went out and did extensive reviews and found out that other payers were paying under \$200 for those lenses. We then convinced the Health Care Financing Administration to develop a regulation to reduce it to \$200.

Well, the Congress actually beat them to it and changed the law, and changed the reimbursement to \$200. That one change saved Medicare \$500 million over 5 years. The industry howled and said, "There's no way we can be competitive with this." We agreed to take another look at this 18 months after that regulation went into effect, and, to our surprise, we found that they were buying the lenses for \$126, on average. So Medicare then reduced its payment to \$150 and saved another \$18 million a year.

So the marketplace is flexible. There's a lot of technology, a lot of pricing changes, and Medicare can't adjust fast enough to it.

Mr. HORN. One other question: Has there been any discussion between the Inspector General and the Internal Revenue Service on amortization schedules of some of this equipment, and is there a relationship between the amortization schedule and what you are seeing billed here numerous times to pay that? What kind of discussions, if any, have gone on?

Mr. MANGANO. To be honest with you, I'm not aware of any with the Internal Revenue Service.

Mr. HORN. I just wonder if any should go on.

Mr. MANGANO. We will check into that.

Mr. HORN. I think there might be something there.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you.

At this time, I call on the ranking member, Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me begin by saying that I'm concerned about the coordination, period. Even where we are today, and, of course, when I look at the numbers, the fact that you were able to retrieve \$440 million, but they are saying that fraud was as high as \$25 billion. My concern is, how many agencies do you have that are actually pursuing this?

Mr. MANGANO. In the Medicare area, our department, our Inspector General's Office is the primary unit that is involved with this. We do work very closely with HCFA, which has special fraud units in each of their contractors across the country. As they begin to develop leads on cases, they will transfer them to us. The FBI has been doing some work also, recently, over the last several years, in this area. They are devoting some attention to it.

In the Medicaid area, we have the State Medicaid fraud control units that are primarily looking at fraud in Medicaid within their States.

Mr. TOWNS. My question is, though, how do you communicate? In other words, how do you find out what they are doing, and how do they find out what you are doing, to make certain that we are not wasting dollars, that we are not engaged in fraud and abuse within those agencies?

Mr. MANGANO. One of the things that we do with the Federal Bureau of Investigation, I think, is a model. That is that one of their staff members sits in our office, and one of our staff members sits in theirs. We go over cases every day that we are working on and they are working on.

Under the Operation Restore Trust, that I believe Mr. Shays talked about a little earlier, of the 240 cases that we are operating, 70 are with other agencies. Once a month, the Inspector General meets with high-level officials at the Department of Justice to go over our significant cases.

Typically, what we find is not that there is duplication, but that others would like us to work with them even more intensely than we do right now. In almost every case that the FBI operates in the health care field, they want us working it with them. Our people have been trained in the Medicare area and have worked it a number of years. The FBI is just, relatively, getting started. So I think the working relationship is very productive. They lend a lot of things, as well, to the investigations.

Mr. TOWNS. You testified that you need statutory authority to react more quickly to adjust reimbursement levels. However, we have behind you the two witnesses from industry, and I read their testimony, and I noticed that, in their testimony, they say that the provision in H.R. 3224 that grants you this authority deprives providers of due process.

How do you respond to that concern?

Mr. MANGANO. Well, I would say this: If you had to go buy a glucose monitor yourself, and your insurance wasn't paying for it, and you could go down to the local drug store, and you saw a model that was \$50 and you saw one that was \$200, and you did research and found out that both of them were of equal quality, which would you want to buy?

Mr. TOWNS. Knowing me, my wife would make certain that I buy the one that cost less.

Mr. MANGANO. Right. So the simple fact of it is that when we find that there are no qualitative differences, why shouldn't Medicare pay less? It's what you would do.

Mr. TOWNS. Right. Well, I agree with that. But I think the point is that, you know, my real concern is—I might as well just sort of lay it on the table here. I tried to avoid it, tried to dance around it.

Here we are, we're talking cutting Medicaid, we're talking about cutting Medicare, we're talking about cutting people out, in terms of staff people from all these different agencies. Now, once we cut Medicaid and once we cut Medicare, there are going to be more problems. I mean, there are no ifs, ands, and buts about it. I can only think of the nursing home situation in my own State many, many years ago, before we came up with some rules and regulations.

Thinking in terms of that and looking at where we are going, in terms of all the cuts that we are making, I'm not sure that we will be successful in creating the atmosphere and climate, in terms of bringing on additional investigators to be able to deal with this problem. Has your office thought about this at all? Because if you do not have the staff and don't have the resources, how do you solve this problem?

Mr. MANGANO. Well, I don't think we can solve it. I think we can work away at it. Some of the significant things that we can do, in addition to the investigations, are the audits that we do of providers and the evaluations when we are looking at impact, nationally. Some of the changes aren't just immediate market pricing but legislative changes that can change the way that we purchase our goods and services.

There's no doubt that there are going to be a lot of howls as Medicare and Medicaid begin to ratchet down or save money. But our position would be this: Why not save that money by taking it away from those who are unjustly enriching themselves, as opposed to taking services away from people who need them?

Mr. TOWNS. I agree with that. My concern is that, being around here now for a lot of years, how do we create the atmosphere and climate within this body to be able to do what is right? The point is, everybody is against fraud and abuse; there's no doubt about it. But if you say you want to bring on 150 more agents to go out and find out, then they say, "No, no, no."

So the point I'm saying is that you can't have your cake and eat it too. If we're going to go look for fraud and abuse, we have to have somebody to go find it. You can't just say it without putting the resources behind it. And I'm not seeing that kind of commitment coming from this side.

Mr. MANGANO. Actually, we've been extremely delighted with the kinds of bills that we're seeing now, your bill, Mr. Shays', and Mr. Schiff's bill, the House bill, the Kassebaum-Kennedy bill, which all have more resources for our office, the Department of Justice, and the Health Care Financing Administration. Those resources will be well spent.

I just want to give you one statistic that ought to be frightening. That is that our office has been so resource-limited in recent years that we do not have an office in 24 States of this country. So if there is fraud being committed there, it's awfully hard for us to investigate it.

Mr. TOWNS. In half of the States you do not have offices.

Mr. MANGANO. That's correct. And we think that the kinds of resource commitments that are in the bills that are now either being proposed or have been carried in the House and Senate will go a long way in helping us redress that problem.

Mr. TOWNS. Well, it seems to me it should be easy to make the case, because when you look at the numbers, when you look at \$440 million you were able to retrieve, but, at the same time, GAO is saying that there is at least \$25 billion that we could have gotten. Of course, some people are saying it even goes higher than that, but I would even just look at the \$25 billion.

So it seems to me that we should aggressively pursue this, and whatever it takes to do it, we should just move forward to do it. And I'm hoping that the commitment stays on this side to give the kind of staff. But my experience has been, when it comes down to putting the resources where they are supposed to go, we have a tendency to forget.

Mr. MANGANO. We agree.

Mr. TOWNS. So thank you very much for your testimony, and we really look forward to working very closely with you. I think that fraud and abuse is something that we must begin to deal with in a very effective manner if we want to provide quality health care for people. Thank you very much.

Mr. MANGANO. Thank you.

Mr. SHAYS. When I was a State legislator, I looked at Congress and I remember seeing hearings like that, and I got outraged, and we still have the damn problem. And I look at the statute. The statute was written in 1987, and it says, "The Secretary, by regulation, shall describe the factors to be used in determining the cases of particular items or services in which the application of this subsection results in the determination of reasonable charge that, by reason of its grossly excessive or grossly deficient amount, is not inherently reasonable."

I'm wondering why it has to be "grossly excessive"? I would think that if it was excessive, especially—and then it goes down, I mean, and it gives the criteria. "The Secretary may provide, by an increase or decrease in the reasonable charge, otherwise recognize under this section, with respect to a specific physician service, only in accordance with the criteria set in paragraph—" that I just read, and then these other factors—"prevailing charges for a service in a particular locality are significantly in excess of or below prevailing charges in other comparable localities."

This process takes 2-plus years. We know, in this competitive marketplace, prices change daily, weekly, monthly. Why would we tie both hands, both feet, and then say, "OK. You've got to run."

Mr. MANGANO. As I've testified, I agree with you, we should not do that. We're losing too much money in the meantime.

Mr. SHAYS. Give me the best argument for why we should do it.

Mr. MANGANO. The argument that some would give is to say that you need to give persons in the industry, as well as the public, an opportunity to comment on the changes that you're planning to make, that we need time to adjust our prices, we need time to convince you that your decisions are erroneous, are correct.

Mr. SHAYS. Let me give you this scenario. I can understand the industry saying, "You are so large that you can basically determine price because you are the primary player." I can understand that. But what could an argument be that we would pay more than consumers pay, more than other Government agencies pay, what possibly could be the argument for that?

Mr. MANGANO. I'm afraid that I can't give you one.

Mr. SHAYS. If we set a price, do we force the industry to sell to us at that price? Can't they refuse?

Mr. MANGANO. Absolutely. Usually fee scales are established in which Medicare will pay either a range or a specific fee. There's usually a floor and a ceiling. And when persons submit their bills to the local contractor in their area, the contractor has some latitude to adjust that price, but it's not a huge latitude there.

Mr. SHAYS. So we basically don't have competition in this industry of any consequence.

Mr. MANGANO. That's absolutely correct.

Mr. SHAYS. Your testimony before us is that we're not just wasting tens of millions of dollars, not just hundreds of millions of dollars, but billions of dollars.

Mr. MANGANO. I believe so. Some of these areas that I talked about, we challenged half of the charges. That's extraordinary.

Mr. SHAYS. Mr. Schiff and I had two bills. One bill was making waste, fraud, and abuse, particularly abuse and fraud, a Federal offense, which it isn't now, and to make it all-payer, which means that it's private sector and public that it's a Federal offense.

We got it in the bill that everyone argued should be clean. They just wanted it to be for pre-existing condition and transportability, and the argument was keeping it clean. Frankly, I viewed that bill as a dirty bill if it didn't include getting after the crooks, which was to put fraud, waste, and abuse in there, a Federal offense, and all-payer. We got it in the House version; it's still in the Senate version. I know certain industries are trying to take it out in conference.

Now, the other thing we tried to get in but we didn't succeed was simply the bill that I submitted with Mr. Schiff, and that was to say that the HHS, the Secretary, could put an interim price. In other words, instead of going through this process and waiting 3 years to buy the product at the price that everyone else pays, we would allow a quicker version, an interim price, before you went through the whole system.

Is there a negative to that proposal?

Mr. MANGANO. No. I think that's a real step in the right direction. The ability for HCFA to make a quick determination and then go through the rest of the process, I think, is a useful one.

Mr. SHAYS. I would appreciate it if your office would go to the Ways and Means Subcommittee on Health, with Bill Thomas, and Mr. Kahn, Chip Kahn, who is the staff person, and encourage them to move forward on this legislation. We had a hearing on this, and they heard this legislation a few days ago.

Mr. MANGANO. OK.

Mr. SHAYS. Let me say to you that I am determined that we are going to pursue this. When I leave this hearing today, I am going to specifically go to the Speaker's office, and I am going to specifically talk about this issue. And I would encourage your office to contact the Speaker's office, as well.

Mr. MANGANO. OK.

Mr. SHAYS. Thank you.

Any other Member?

Mr. MANGANO. In the interim, I did get some information for you.

Mr. SHAYS. I would like that, the \$600,000.

Mr. MANGANO. Yes. There are 27 cases open. We didn't get the particular case yet, but we can get that over the next day.

Mr. SHAYS. Give me a sense of the \$600,000, though. Do you know if that company is still in business with us?

Mr. MANGANO. I know we prosecuted them, so I am almost sure they would have had to have been excluded from the program. We will get you the details.

Mr. SHAYS. Why would you make an assumption just because they were prosecuted they were excluded?

Mr. MANGANO. Because if they are prosecuted and found guilty, it's an automatic exclusion from the program.

Mr. SHAYS. Unless they change their number.

Mr. MANGANO. Yes. It is possible. If the company was found guilty of fraud but not the individuals, the individuals could go start a new company and be back in business.

Mr. SHAYS. You have testified in the past that that's exactly what happens.

Mr. MANGANO. Yes.

Mr. SHAYS. In your report, you say you have done a number of studies saying, "filing claims for equipment that was never delivered, billing for high-cost equipment when lesser cost equipment was actually provided, 'uncoding,' billing for the component parts of a piece of equipment instead of the entire unit, 'unbundling,' delivering equipment that has no medical benefit, or delivering medical equipment to beneficiaries who do not need it; Medicare reimbursement rates that are clearly excessive when compared to payments made by other payers or compared to the wholesale cost or market discounts," which is really what we're talking about today, in particular.

The bottom line is, you've done your job; you've given it to Congress, and Congress, for years, hasn't done its job, collectively. It is not a partisan issue. Somehow some providers get to certain key Members of Congress, and they basically have convinced them that it is unfair for the Government, which is the largest purchaser, to be able to determine price. And they have gotten a system like this

that hasn't been changed because of the political process, and the public is getting screwed. You've done your job; we've got to do our job.

Mr. Horn.

Mr. HORN. I agree with that comment, and I think we should ask, even though it's a very politicized office by its nature, ask the Secretary of HHS, where these two areas currently reside, for suggestions to streamline the process so the public interest could be served. That's one thing.

Then, frankly, I would like to have the suggestions of the Inspector General, a little more neutral source and a little more objective source than the Secretary of HHS, regardless of administration, as to how this could be developed in relation to what already exists. You've got Army hospitals, VA hospitals. You've got every HMO in the Nation with bulk purchasing that immediately gets them volume discounts. And yet Medicare is the biggest game in town. It's the elephant in the jungle.

We don't take advantage of that tremendous purchasing power that Medicare and Medicaid have. It just seems to me, when you watch the taxpayers being gouged on these fees, and this whole process, that we need to get the administration on record as to what they want to do. We need to get the Inspector General on record. And we need to get GAO into this, to look at the private sector, the semipublic sector, and the public sectors, and see if we can't get a process that makes some sense here.

Two years makes no sense. The Secretary ought to have the discretion, or if we make these independent agencies, as we did with Social Security, the administrator of the Health Care Financing Administration ought to have that discretion to get the show on the road and preserve the public interest.

You sort of get speechless when you get into this area.

Mr. SHAYS. Yes. But that's the problem, we've been speechless and therefore we haven't done anything.

Mr. HORN. Well, we haven't been speechless if we had a chance to do something. I only came here in 1993, folks. I'm not going to accept the sins of the past. I want to change the sins of the past.

Mr. SHAYS. I want to blame you like everyone else.

Mr. HORN. Yes. Well, blame yourself, my friend. But you were in the minority. You couldn't do anything about it anyhow.

Mr. SHAYS. No.

Mr. TOWNS. Before I respond.

Mr. SHAYS. I'm going to give you a chance to respond. I'm going to blame myself. I'm going to blame myself, and I'm going to blame everyone who has heard this, seen it, and not done anything about it. But we're trying now. We have a bill. We wanted it attached to the so-called "keep it clean" health care bill. But, in my judgment, if it doesn't include these provisions, it's a "dirty" health care bill.

Mr. TOWNS. On that note, I associate myself with your remarks, and I reserve my comments.

Mr. MANGANO. Thank you very much.

Mr. SHAYS. Our next panel is representing the industry. I do want to say that there are a whole host of very reputable individuals in this industry. We're going to just try to make sure we are

able to let the honest ones operate, and the dishonest ones, get them out of business.

With that, I would call on our witnesses. Darrell Foreman, Home Health Care Market Group, Health Industry Distributors Association, and Rick Doherty, chair of the Legislative Policy Committee, National Association for Medical Equipment Services.

I am going to ask the Inspector General—is he still here? Could someone get the Inspector General, please?

I would respectfully request the Inspector General stay because there may be comments made, and I may ask you to just come back up. Is that all right?

Mr. MANGANO. Sure.

Mr. SHAYS. Thank you. I know you're very busy, but I just would appreciate that.

Gentlemen, if you both would rise. We actually swear in everyone, including, when I'm chairman, Members of the Congress. If you would raise your right hands.

[Witnesses sworn.]

Mr. SHAYS. We will start with you, Mr. Foreman. We welcome your testimony. It is such an important issue.

I ask unanimous consent that all members of the subcommittees be permitted to place any opening statements in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

I also ask unanimous consent that our witnesses be permitted to include their written statements in the record. Without objection, so ordered.

I make this point to you that you are our third and final panel. We don't have anyone following you. You are welcome to give your statement so that you are satisfied that you have covered the territory. So we're going to put the clock on, but I'm going to give you some leeway.

Mr. Foreman.

STATEMENTS OF DARRELL FOREMAN, HOME HEALTH CARE MARKET GROUP, HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION; AND RICK DOHERTY, CHAIR, LEGISLATIVE POLICY COMMITTEE, NATIONAL ASSOCIATION FOR MEDICAL EQUIPMENT SERVICES

Mr. FOREMAN. Thank you. Before I begin, I would like to thank the kind statements given by Mr. Mangano to our industry, especially the part about the "highly ethical organizations" that will follow him.

I would just like to go on with just one thing. The number that is discussed at this meeting and throughout the industry is that 10 percent of everything that is billed within our industry is fraudulent. That means that 90 percent of what is billed is actually valid billing.

Mr. SHAYS. Yes, that is true, but 10 percent of half of \$178 billion is a good chunk of dollars.

Mr. FOREMAN. But our industry represents approximately 2 to 4 percent of that \$178 billion.

Mr. SHAYS. I could somehow accept 1 percent; somehow 10 percent gets me.

Mr. FOREMAN. Thank you.

Good morning. My name is Darrell Foreman, and I am president of Happy Harry's Health Care, a home medical equipment provider in Delaware. My 12-year-old company is a full-line home medical equipment company providing respiratory products and services, wheelchairs, beds, walkers, and other home medical equipment, supplies, and services to Medicare beneficiaries, Medicaid recipients, and private pay patients for use in their homes.

My testimony today is on behalf of the Health Industry Distributors Association, that's HIDA. I serve as regional director on HIDA's home care market group.

Mr. Chairman, I appreciate the opportunity to testify before your subcommittee today to discuss H.R. 3224, the Health Care Fraud and Abuse Prevention Act of 1996. Let me briefly say that HIDA fully supports this bill to the extent it would combat waste, fraud, and abuse in Medicare and Medicaid programs.

For many years, HIDA has worked with Congress, HCFA, and the Office of the Inspector General and has made recommendations to ensure that beneficiaries receive medically necessary products and services without any fraudulent or abusive practices. My testimony today will focus on section 303 of H.R. 3224, a provision which would expedite payment adjustments for durable medical equipment under Part B of the Medicare program, based upon inherent reasonableness, which I will refer to as IR.

At the outset, I believe that the language in the provision is a little vague and unclear. For example, I and we are not sure what is meant by "one year after the Secretary initially proposes." Does this mean the date the proposed rule is issued or the date an announcement is made by the Government in a meeting with the industry?

Regardless of what is meant by the bill's current language, HIDA and providers such as myself are seriously concerned that section 303 of H.R. 3224 would place far too much arbitrary authority in the hands of an administrative agency. Mr. Chairman, it would be ironic that this Congress, which talks about less government bureaucracy, would, in fact, propose to increase the power of the unelected bureaucracy.

The public rulemaking process was created to ensure the affected parties have an opportunity to be heard. This provision, if implemented, would result in the implementation of interim rules made effective prior to review by HHS of relevant data and all relevant factors.

The impact on businesses, the vast majority being small, like my own company, which provide valuable services to Medicare beneficiaries, and the impact on the quality of patient care in the Medicare program would be at risk if such arbitrary, unaccountable power were handed to an administrative agency by Congress. We believe the current IR process is an effective means of gathering the truth about Medicare payments and has numerous built-in safeguards which protect affected parties from hastily made administrative decisions.

Let me describe briefly the current IR process. To change Medicare reimbursement rates through the IR process, HCFA must substantiate that the current Medicare rates are grossly excessive or

grossly deficient and not inherently reasonable. The agency must then consult with the industry that will be affected by any change in the reimbursement amount. HCFA will issue a proposed rule that substantiates the fact that current Medicare rates for the item in question are grossly excessive or grossly deficient.

Industry responds with comments relevant to the proposed change. Once HCFA reviews and analyzes the comments of the proposed rule, HCFA is required to issue a final rule which explains the factors and data that they took into consideration, including the economic justification for any uniform fee or payment limit established.

Mr. Chairman, as you can see, the IR process is thorough but not unwieldy. It flows naturally and helps ensure the development of sound public policy. Further, it is consistent with the intent of the Administrative Procedures Act, a law enacted in 1946 to set uniform standards for the thousands of government administrative actions affecting the public.

What impact would passage of this bill have? You need look no further than what happened last year in the case of home oxygen when HCFA was under the impression that Medicare's payment for home oxygen was excessive. HIDA, along with other industry representatives, was invited to meet with officials of HIDA to discuss the agency plans to pursue its IR authority to reduce payments for home oxygen.

Based on detailed input and data from industry, HCFA told HIDA that it could not justify reducing oxygen cost based on the changing technology argument. In other words, the industry consultation time period proved to be educational for HCFA and ultimately beneficial to the millions of home oxygen patients who rely on home oxygen therapy.

Another argument originally offered by HCFA to lower home oxygen rates was that other payers pay less for home oxygen. However, HCFA's comparison of other purchasers found that at least 95 percent of the other payers, including private payers, State Medicaid programs, and other government payers are consistent or higher than the Medicare rates. The IR process for home oxygen revealed that Medicare is consistent with other payers and is not grossly excessive in its current rates for home oxygen.

A careless reduction in home oxygen would have had a devastating impact on the services currently provided to home oxygen beneficiaries, and thus the IR process, with its built-in safeguards, worked to protect beneficiaries from potentially losing these vital services. Further, many home oxygen companies would have been forced out of business based on an ill-informed interim rule.

Mr. Chairman, HIDA appreciates the opportunity to testify before your subcommittee today. I will be glad to address any questions you or your colleagues might have.

[The prepared statement of Mr. Foreman follows:]

EXECUTIVE SUMMARY

HIDA is extremely concerned about section 303 of H.R. 3224, which would require the Health Care Financing Administration (HCFA) to adjust payments for an item of durable medical equipment within one year of when the Secretary of the Department of Health and Human Services initially proposes to make the adjustment.

The language in section 303 of H.R. 3224 is vague and unclear. What exactly is meant by "one year after the Secretary initially proposes?" Does this mean the date the proposed rule is issued? Does it apply to an announcement by the government at a meeting with industry? Does it apply when HCFA testifies at a Congressional hearing? If, for example, "Secretary initially proposes" did not apply strictly to a proposed rule, the law could actually require that an interim final regulation be issued prior to or simultaneous with the issuance of a proposed rule. As a result, HCFA could be forced to make a misinformed decision.

Section 303 of H.R. 3224 would place far too much arbitrary authority in the hands of an administrative agency. The public rulemaking process was created to ensure that affected parties have an opportunity to be heard. Section 303 of H.R. 3224, if implemented, would result in the implementation of interim rules made effective prior to review by the HHS of relevant data and all relevant factors. As a result, important rights of interested parties may be adjudicated for long periods of time under procedures that were not subject to notice and comment rulemaking. The impact on businesses (the vast majority being small businesses) which provide valuable services to Medicare beneficiaries and the impact on the quality of patient care in the Medicare program would be at risk if such arbitrary, unaccountable power were handed to an administrative agency by Congress. It would be ironic that this Congress, which talks about less government bureaucracy, would in fact propose to increase the power of the unelected bureaucracy.

The current IR process is an effective means of gathering the truth about Medicare payments. The IR process has numerous built in safeguards which protect affected parties from hastily made administrative decisions. The following are important steps that must be followed in the IR process:

- HCFA must consult with industry.
- HCFA must issue in the *Federal Register* a proposed rule, with a comment period of at least 60 days, which would substantiate the fact that current Medicare rates for the item in question are "grossly excessive" and "not inherently reasonable."
- HCFA is required to review and take into consideration all comments responding to the proposed rule before issuing a final rule with an effective date.

The IR process provides the public with notice and an opportunity to comment, and requires the agency to justify its results.

What impact would passage of section 303 of H.R. 3224 have? You need look no further than what happened last year in the case of home oxygen. Last year, HCFA was under the impression that the Medicare payment for home oxygen was excessive. However, based on input and data from industry, HCFA discovered data that found the Medicare payment for oxygen was in fact comparable to other payors. In fact, HCFA actually found that at least 95% of the other payors of oxygen, including private payors, State Medicaid programs, and other government agencies, charge the same or higher rates than Medicare.

If section 303 of H.R. 3224 were in effect, HCFA may have been required by law to issue an interim home oxygen rule that substantially cut Medicare home oxygen rates. This would have had a devastating impact on the home oxygen services that companies now provide to Medicare beneficiaries, thereby negatively impacting quality care and access to services that beneficiaries now enjoy. Further, many home oxygen companies would have been forced out of business based on an ill-informed interim rule.

The IR process was completed in the case of blood glucose monitors within one year from the date of the proposed rule to the date of the final rule. HCFA issued a proposed rule January 6, 1994. A final rule was published January 17, 1995 in the *Federal Register*. While HIDA did not agree with the final determination concluded by HCFA, the IR process did offer necessary time for affected parties to prepare comments, submit data and highlight issues of concern. In turn, HCFA was able to review this information and respond accordingly. The process reached a conclusion and allowed affected parties the opportunity to state their cases.

I. Introduction

Good morning. My name is Darrell Foreman, and I am President of Happy Harry's Health Care, Inc., a home medical equipment provider in Delaware. My 12-year old company is a full-line home medical equipment company, providing respiratory products and services, wheelchairs, beds, walkers and other home medical equipment, supplies and services to Medicare beneficiaries, Medicaid recipients and private pay patients for use in their homes.

My testimony today is on behalf of the Health Industry Distributors Association (HIDA). I serve as Regional Director on HIDA's Home Care Market Group. HIDA is the national trade association of home care companies and health and medical product distribution firms. Created in 1902, HIDA represents over 800 home care companies and wholesale and retail medical product distributors with nearly 2000 locations. Pursuant to a physician prescription, HIDA members provide durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) services to Medicare beneficiaries who are being treated in their homes and to beneficiaries residing in nursing homes.

Mr. Chairman, I appreciate the opportunity to testify before your Subcommittees today to discuss H.R. 3224, "The Health Care Fraud and Abuse Prevention Act of 1996." Let me briefly say that HIDA fully supports this bill to the extent it would combat waste, fraud and abuse in the Medicare and Medicaid programs. For many years, HIDA has worked with Congress, HCFA, and the Office of Inspector General, and has made many recommendations to ensure that beneficiaries receive medically necessary products and services without any fraudulent or abusive practices.

My testimony today will focus on section 303 of H.R. 3224, "The Health Care Fraud and Abuse Prevention Act of 1996."

II. Section 303 of H.R. 3224 Would Place Far Too Much Arbitrary Authority In the Hands Of An Administrative Agency

Mr. Chairman, I appreciate the opportunity to testify before your Subcommittees today to discuss Section 303 of H.R. 3224, which would expedite payment adjustments for durable medical equipment under Part B of the Medicare program based upon inherent reasonableness (IR). This provision states that the "Secretary [of the Department of Health and Human Services (HHS)] shall make an adjustment in payment for an item... through issuance of an interim final regulation issued no later than 1 year after the Secretary initially proposes to make the adjustment."

At the onset, I should point out that the language in Section 303 of H.R. 3224 is vague and unclear. What exactly is meant by "1 year after the Secretary initially proposes?" Does this mean the date the proposed rule is issued? Does it apply to an announcement by the government at a meeting with industry? Does it apply when a

Health Care Financing Administration (HCFA) official testifies at a Congressional hearing? If, for example, "Secretary initially proposes" did not apply strictly to a proposed rule, the law could actually require that an interim final regulation be issued prior to or simultaneous with the issuance of a proposed rule. As a result, HCFA could be forced to make a rash decision based on little or no input from the public.

Regardless of what is meant by the bill's current language, HIDA is gravely concerned that Section 303 of H.R. 3224 would place far too much arbitrary authority in the hands of an administrative agency. The public rulemaking process was created to ensure that affected parties have an opportunity to be heard. This bill, if implemented, would result in the implementation of interim rules made effective prior to review by the HHS of relevant data and all relevant factors. As a result, important rights of interested parties may be adjudicated for long periods of time under procedures that were not subject to notice and comment rulemaking. The impact on businesses (the vast majority being small businesses) which provide valuable services to Medicare beneficiaries and the impact on the quality of patient care in the Medicare program would be at risk if Congress handed to an administrative agency such arbitrary, unaccountable power. Mr. Chairman, it would be ironic that this Congress, which talks about less government bureaucracy, would in fact propose to increase the power of the unelected bureaucracy.

The current IR process is an effective means of gathering the truth about Medicare payments. The IR process has numerous built in safeguards which protect affected parties from hastily made administrative decisions. This process provides the public with notice and an opportunity to comment, and requires the agency to justify its results. The effectiveness and necessity of the IR process was best summed up by Bruce C. Vladeck, Administrator of HCFA, in a November 15, 1995 letter to Congressman Charlie Norwood of Georgia responding to an inquiry about home oxygen. Stated Vladeck:

As required by law, before proposing an adjustment in Medicare payments for home oxygen, we consulted with industry representatives in order to solicit their comments on the appropriateness of an adjustment. We continue to receive numerous comments from the industry, both with respect to the data and the rationale in making an inherent reasonableness determination. We are carefully reviewing these comments and will take them into account in drafting a proposed notice. After publication of a proposed notice in the *Federal Register*, interested parties will have an additional 60-day comment period. Should HCFA decide after reviewing these comments that Medicare's payment amounts for home oxygen are excessive, we will then publish a final notice in the *Federal Register* which will address all of the home oxygen industry's comments...Thank you for your interest in the Medicare program. ***I can assure you that the process for applying the inherent reasonableness provision of the law ensures that our findings will be credible*** [emphasis added].

The IR process is necessary to preserve integrity and accountability in the process.

III. If Enacted, The Bill Would Be Extremely Harmful To Beneficiaries And Those Businesses That Provide Valuable Services To Beneficiaries

What impact would passage of this bill have? You need look no further than what happened last year in the case of home oxygen. Last year, the Health Care Financing Administration (HCFA) was under the impression that the Medicare payment for home oxygen was excessive. However, the built in safeguards of the IR process proved to be educational for HCFA. Based on input and data from private payors and the industry, HCFA discovered data that found the Medicare payment for oxygen was in fact comparable to other payors. In fact, HCFA actually found that at least 95% of the other payors of oxygen, including private payors, State Medicaid programs, and other government agencies, reimburse the same or higher rates than Medicare.

If Section 303 of H.R. 3224 were in effect, HCFA may have been required by law to issue an interim home oxygen rule that substantially cut Medicare home oxygen rates. This would have had a devastating impact on the home oxygen services that companies now provide to Medicare beneficiaries, thereby negatively impacting quality care and access to services that beneficiaries now enjoy. Further, many home oxygen companies would have been forced out of business based on an ill-informed interim rule.

Mr. Chairman, beneficiaries who receive substantial oxygen services from suppliers, including 24-hour, seven day a week emergency support so that oxygen service is not interrupted, and businesses who provide a valuable service in the Medicare program, are glad that Section 303 of H.R. 3224 was not law in 1995.

IV. The Current Inherent Reasonableness Process Ensures A Thorough Review Of Medicare Payments By HCFA

The current IR process has established proper checks and balances to ensure that affected parties have a meaningful opportunity to be heard. This process is not unduly burdensome. Rather, as I will outline, it is a necessary and important process that protects beneficiaries, providers, and the government from a misinformed and hastily made decision.

IR Standard: Grossly Excessive Or Grossly Deficient

To change the Medicare reimbursement rates through the IR process, HCFA must substantiate that the current Medicare rates are "grossly excessive" or "grossly deficient" and "not inherently reasonable." This is a strong burden which HCFA must pass. This explains why it is essential that all data and all issues are clearly addressed prior to issuance of a Medicare reimbursement change.

Factors To Consider In IR Determination

The following are factors, pursuant to Section 1842(b)(8) of the Social Security Act (SSA), that HCFA must consider in an IR determination (HCFA can consider other relevant factors also):

- Prevailing charges for a service in a particular locality are significantly in excess or below prevailing charges in other comparable localities
- There have been increases in charges for a service that cannot be explained by inflation or technology.
- The charges do not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.
- The prevailing charges or a service are substantially higher or lower than the payments made for the service by other purchasers in the same locality.
- The potential impacts on quality, access, and beneficiary liability of the adjustment.

HCFA must conclude, based on these and other factors, that the Medicare rate for the particular item being reviewed is "grossly excessive" or "grossly deficient." The agency must then, pursuant to the law, undergo the following essential steps to ensure that their original thoughts are indeed correct.

Industry Consultation

Section 1842(b)(9) of the SSA requires the agency to appropriately consult with the industry likely to be affected by any change in the reasonable charge. This consultation process has taken the form of a meeting with trade associations and other representatives of the potentially impacted industry. In the past, HCFA has provided written notice to HIDA and other industry representatives for such a meeting.

Proposed Rule

HCFA is then required to issue a proposed rule that substantiates the fact that current Medicare rates for the item in question are "grossly excessive" or "grossly deficient." The agency must publish a notice of such proposal in the *Federal Register* with at least 60 days provided for public comment. The implementing regulations issued by the HHS (See 42 CFR 405.502) require HCFA to issue a proposed rule that accounts for the proposed charge or methodology to be established with respect to a service as well as the factors and data that HCFA took into account in determining the charge or methodology. This includes the economic justification for a uniform fee or payment limit if it is proposed.

Final Rule

Once the comments are reviewed and analyzed, HCFA is required to issue a final rule in the *Federal Register* which explains "the factors and data that HCFA took into consideration, including the economic justification for any uniform fee or payment limit established" (See 42 CFR 405.502).

Mr. Chairman, as you can see, the IR process is thorough but not unwieldy. It flows naturally and helps ensure the development of sound public policy. Further, it is

consistent with the intent of the Administrative Procedure Act (APA), a law enacted in 1946 to set uniform standards for the thousands of Government administrative actions affecting the public. Section 553 of the APA requires that "general notice of proposed rulemaking shall be published in the *Federal Register*" and requires each agency to "give interested persons an opportunity to participate in the rulemaking through submission of written data, views or arguments."

V. Home Oxygen Example Signifies Importance Of Effective IR Process

As I stated earlier, the IR process regarding home oxygen is a good example of why a careful analysis and review of data by HCFA is necessary. I'd like to briefly delve into a little more detail on this issue

In the summer of 1995, HIDA, along with other industry representatives, was invited to meet with officials of HCFA to discuss the agency's plans to pursue its inherent reasonableness authority to reduce payments for home oxygen. Initially, HCFA believed that the Medicare payment for home oxygen was excessive.

Change In Technology Argument Was Found Not To Be Valid

One of the key factors cited by HCFA which they believed justified reduced oxygen rates stemmed from 42 CFR 405.502(g)(1)(iv) which states that the [current] charges "do not reflect changing technology, increased facility with that technology, or changes in acquisition, production or supplier costs." HCFA's original data discovered that 68.2% of beneficiaries utilized concentrator systems in 1987 while 31.8% of beneficiaries utilized other (gas & liquid) systems. In 1993, HCFA found that 87.13 percent of beneficiaries utilized concentrator systems compared with 12.87% using other (gas & liquid) systems. HCFA also analyzed 1987 expenditures for oxygen based on concentrator use and all other (gas & liquid) and divided this figure by the number of beneficiaries per modality. The resulting figure was the average monthly payment amount which resulted in \$287 per month for concentrator systems and \$404 per month for all other (gas and liquid systems). HCFA then calculated the percentage changes in 1993 and plugged in the resulting savings which would occur. This analysis, according to HCFA, led to a conclusion that oxygen fees should be reduced 6.82%.

HCFA's analysis sounds good. However, in reality it was flawed. Industry provided data to HCFA which showed that the agency's analysis did not breakdown the percent changes in use of gas versus liquid nor did it address the fact that in 1987 oxygen contents were billed separately, while in 1993 oxygen contents are included in the base fee. In addition, HCFA did not account for the substantial increase in the number of patients using portable oxygen which results in a much higher cost to suppliers. Based on this input from industry, HCFA told HIDA that it could not justify reducing oxygen costs based on the changing technology argument. In other words, the industry consultation time period proved to be educational for HCFA and ultimately beneficial to the millions of home oxygen patients who rely on home oxygen therapy.

HCFA Found That Medicare Rates Are Reasonable When Compared To Other Payers
 Another argument originally offered by HCFA to lower home oxygen rates was that the "prevailing charges for a service are substantially higher or lower than the payments made for the service by **other purchasers** (emphasis added) in the same locality." See 42 CFR 502 (g)(1)(viii). However, as stated earlier, HCFA's comparison of other purchasers found that at least 95% of the other payors, including private payors, State Medicaid programs, and other government payors are consistent or higher than the Medicare rates.

The IR process for home oxygen has revealed that Medicare is consistent with other payors and is not "grossly excessive" in its current rates for home oxygen. A careless reduction in home oxygen would have had a devastating impact on the services currently provided to home oxygen beneficiaries. The IR process, with its built in safeguards, has therefore worked to protect beneficiaries from potentially losing these vital services.

VI. Blood Glucose Monitors Is Case Of IR Process Resulting In Final Rule

In the case of home blood glucose monitors, the IR process was completed within one year when you measure date of publication of the proposed rule to date of publication of the final rule. In May of 1993, HCFA invited industry to meet with HCFA to discuss HCFA's intent to issue a proposed rule to reduce the Medicare fee schedule amount for home blood glucose monitors. In June of 1993, HIDA and other industry representatives met with HCFA on this issue. This constituted the "industry consultation" phase in the IR process. During this process, HCFA contended that the reimbursement amount for blood glucose monitors should be reduced by the value of the consumer rebates manufacturers use to promote their blood glucose monitor products. HIDA and others argued that the existence of rebates does not relate in any way to the market price of the home blood glucose monitors and is purely a manufacturer's marketing tool. HCFA issued a proposed rule January 6, 1994 attempting to address industry concerns. A final rule was published January 17, 1995 in the *Federal Register*.

While HIDA did not agree with the final determination concluded by HCFA, the IR process did offer necessary time for affected parties to prepare comments, submit data and highlight issues of concern. In turn, HCFA was able to review this information and respond accordingly. The process reached a conclusion and allowed affected parties the opportunity to state their case.

VII. Conclusion

Mr. Chairman, HIDA appreciates the opportunity to testify before your Subcommittee today. I will be glad to address any questions you or your colleagues might have.

Mr. SHAYS. Thank you, Mr. Foreman.

Mr. Doherty.

Mr. DOHERTY. Mr. Chairman and members of the committee, my name is Rick Doherty. I have 16 years experience as a provider of home medical equipment services. My company, Comprehensive Home Health Co., services individuals residing in the metropolitan Boston area. I also serve on the board of directors and am former chair of the National Association for Medical Equipment Services, NAMES, and I am the past president of the New England Medical Equipment Dealers.

I am pleased to testify today on behalf of home medical equipment service providers across the country and to address this committee on the Health Care Fraud and Abuse Prevention Act, H.R. 3224, and the critical role that the HME service industry plays in helping to eliminate fraud and abuse in our Nation's health care delivery system.

NAMES has worked diligently with Congress and the administration to promote access to quality home medical equipment services and to eliminate the few unethical providers who tarnish an otherwise upstanding, reputable industry. NAMES' commitment to this effort is unwavering, and we look forward to working with you to pass strict fraud and abuse legislation in 1996.

H.R. 3224 actively advocates for the eradication of fraudulent and abusive business practices in the health care industry. NAMES agrees with this goal. By creating stiff fines and penalties for fraudulent and abusive health care providers, H.R. 3224 encourages ethical behavior and is consistent with the continuing trend of increasing both the criminal penalties and the number of criminal prosecutions with white collar crime.

While supporting these provisions, NAMES feels that it is imperative to reach a good balance between education and strict enforcement. Education and guidance must be included for both consumers and providers.

H.R. 3224 also contains an amendment affecting a discretionary Medicare payment adjustment mechanism known as inherent reasonableness. The inherent reasonableness process is a device to adjust regularly established Medicare fees which are determined to be grossly excessive or deficient. The process is not an effective device to combat the activities of fraudulent or abusive providers and should not be viewed as a fraud control device by the inclusion of an amendment to IR in this bill.

Section 303 requires the Department of Health and Human Services to change the payment schedule for durable medical equipment within 1 year after the HHS Secretary proposes an adjustment. NAMES believes that this provision needs clarification to ensure that the deliberative process of adjusting Medicare fees is not undermined by imposing arbitrary deadlines for agency action. As it is now drafted, section 303 tends to be vague and subject to a wide degree of interpretation. It could also jeopardize the standard of due process.

For example, we are concerned that one interpretation of section 303 would lead to implementation of a fee schedule change without regard to the findings of a complete and deliberative comparison of the available comparative payment data, as required by the stat-

ute. We are even more concerned that the amendment's interpretation would negate the requirements of the Administrative Procedures Act. The APA requires public notice and comment to occur prior to the implementation of a regulatory change.

As you know, Mr. Chairman, there are well-defined exceptions to the APA. They are: impracticality, lack of necessity, or contrariness to the public interest. We urge the committee not to sweep the entire IR process into one of these narrowly crafted exceptions to the fundamental principles of the APA.

In short, Mr. Chairman, we understand the committee's desire to achieve payment adjustments in a timely manner. However, in reaching for this goal, we hope that you will make every effort to maintain the critically important public protection provided by preimplementation notice and comment.

Medicare law gives HCFA the general authority to make adjustments to Medicare fees when that fee is not inherently reasonable by reason of its grossly excessive or grossly deficient amount and to establish a fee that is "realistic and equitable." Comparison of the selected Medicare fee to other market prices plays a large role in the IR process, but there is no magic formula when a fee becomes grossly excessive.

This final determination is subjective. On the other hand, the statute and regulation are fairly specific about what factors must be considered by the agency. These factors were written with the specific intention of prohibiting HCFA from making arbitrary and hasty reductions.

When HCFA seeks to establish a specific dollar amount limit or special payment method, it must consider all relevant data. In determining the major difficulty in completing the developmental and clearance process, it is instructive to examine previous efforts.

The most time-consuming stage can be traced to HCFA's inability to timely collect and analyze the relevant comparative payment data. The reason is clear. Unlike other Federal agencies, HCFA's primary mission is not oversight and regulation but the administration of a payment system for services and equipment provided to beneficiaries. Quite simply, the agency is not set up to collect and analyze data outside of that data it generates itself; for example, Medicare claims data.

The need to improve the IR authority should not dictate arbitrary deadlines that the agency is poorly structured to undertake. Faster does not necessarily mean better. Instead, the answer should include how to make HCFA a better, more efficient agency overall.

The proposed amendment would require the publication of a payment adjustment action within 1 year. We remind the committee that the adjustment to the glucose monitor fee is the only completed application for the IR process to DME. The glucose monitor IR purportedly took 3 years to complete, yet the time span from publication of the proposed rule to the final rule only took 1 year. The other 2 years apparently were taken up by the development and clearance stages of the IR process.

From the only completed, available example, the time delay appears to be in the development and clearance stages of the process.

As earlier stated, the agency is not set up to collect and analyze data other than its own claims data.

To address the need for timely, comprehensive collection and analysis of comparative payment data, NAMES recommends Congress fund and mandate HCFA to establish a data collection system that includes ongoing monitoring and analysis of other DME payers across the country. By solving an inherent problem with HCFA's development and clearance process, Congress could successfully expedite the IR process without enacting an unclear, inflexible, and arbitrary proposal.

Due to the sensitive and personal nature of services provided to consumers by the health care industry, it is essential that every provider be above reproach in the delivery of quality products and services. Legitimate HME providers, who comprise the vast majority of this small but growing home care industry, have a common interest with policymakers to stop all unethical business practices. This goal can only be achieved, however, through a comprehensive and targeted approach that supports legitimate providers by strengthening the HME service industry while also making it extremely tough on scam operations to conduct business.

NAMES recognizes the objective of Congress to improve the IR process; however, we submit that the problem with the process is inherent in HCFA's inability to continually track other payer sources throughout the year. Adding an arbitrary time line to the IR process will only result in undermining the due process system.

We can solve the inherent data problem by using preventive medicine to fund and mandate HCFA to establish a data collection system that includes ongoing monitoring and analysis of other payers across the country.

Thank you. I would be glad to answer questions.

[The prepared statement of Mr. Doherty follows:]

ORAL TESTIMONY A

Mr. Chairman and Members of the Committee, my name is Rick Doherty. I have 16 years experience as a provider of home medical equipment (HME) services. My company, Comprehensive Home Health Company, services individuals residing in the metropolitan Boston Area. I also serve on the Board of Directors and am a former Chair of the National Association for Medical Equipment Services (NAMES). I am pleased to testify today on behalf of HME services providers across the country and to address this Committee on the Health Care Fraud and Abuse Prevention Act of 1996 (H.R. 3224) and the critical role that the HME services industry plays in helping to eliminate fraud and abuse in our nation's health care delivery

system.

NAMES has worked diligently with Congress and the Administration to promote access to quality HME services and to help eliminate the few unethical providers who tarnish an otherwise upstanding, reputable industry. NAMES commitment to this effort is unwavering and we look forward to working with you to pass strict fraud and abuse legislation in 1996.

H.R. 3224 actively advocates for the eradication of fraudulent and abusive business practices in the health care industry. NAMES agrees with this goal.

By creating stiff fines and penalties for fraudulent and abusive health care providers, H.R. 3224 encourages ethical behavior and is consistent with the continuing trend of increasing both

the criminal penalties and the number of criminal prosecutions with white collar crime. While supporting these provisions, NAMES feel that it is imperative to reach a good balance between education and strict enforcement. Education and guidance must be included for both consumers and providers.

H.R. 3224 also contains an amendment affecting a discretionary Medicare payment adjustment mechanism known as "inherent reasonableness" (IR). The inherent reasonableness (IR) process is a device to adjust regularly established Medicare fees which are determined to be grossly excessive or deficient. The IR process is not an effective device to combat the activities of fraudulent or abusive providers and should not be viewed as a fraud control device by the inclusion of an amendment to IR in this bill.

Section 303 of H.R. 3224 requires the Department of Health and

Human Services (HHS) to change a payment schedule for durable medical equipment (DME) "within one year after the HHS Secretary proposes an adjustment." *NAMES believes that this provision needs clarification to ensure that the deliberative process for adjusting Medicare fees is not undermined by imposing arbitrary deadlines for agency action.*

As it is now drafted, Section 303 is, at best, vague and subject to a wide degree of interpretation. At worst, it could jeopardize the standard of due process.

For example, we are concerned that one interpretation of Section 303 would lead to implementation of a fee schedule change without regard to the findings of a complete and deliberative comparison of the available comparative payment data as required by the statute.

We are even more concerned that the amendment's interpretation would negate the requirements of the Administrative Procedures Act (APA). The APA requires public notice and comment to occur prior to the implementation of a regulatory change. As you know, Mr. Chairman, there are well defined exceptions to the APA. They are impracticality, lack of necessity or contrariness to the public interest. We urge the Committee not to sweep the entire IR process into one of these narrowly crafted exceptions to the fundamental principles of the APA.

In short, Mr. Chairman, we understand the Committee's desire to achieve payment adjustments in a timely manner. However, in reaching for this goal, we hope that you will make every effort to maintain the critically important public protection provided by pre-implementation notice and comment.

Medicare law gives HCFA the general authority to make adjustments to Medicare fees when that fee is not "inherently reasonable by reason of its grossly excessive or grossly deficient amount and to establish a fee "that is realistic and equitable." Comparison of the selected Medicare fee to other market prices plays a large role in the IR process, but there is no magic formula for when a fee becomes "grossly excessive." This final determination is subjective. On the other hand, the statute and regulation are fairly specific about what factors must be considered by the agency. These factors were written with the specific intention of prohibiting HCFA from making arbitrary and hasty reductions.

When HCFA seeks to establish a specific dollar amount limit or special payment method, it must consider all "relevant data."

In determining the major difficulty in completing the developmental and clearance process it is instructive to examine previous efforts. The most time consuming stage can be traced to HCFA's inability to timely collect and analyze the relevant comparative payment data. The reason is clear. Unlike other Federal agencies, HCFA's primary mission is not oversight and regulation of the industry, but the administration of a payment system for services and equipment provided to beneficiaries. Quite simply, the agency is not set up to collect and analyze data outside of that data that it generates itself, i.e. Medicare claims data.

The need to improve the IR authority should not dictate arbitrary deadlines that the agency is poorly structured to undertake. Faster does not necessarily mean better. Instead, the answer should include how to make HCFA a better, more

efficient agency overall. The proposed amendment would require the publication of a payment adjustment action within one year. We remind the committee that the adjustment to the glucose monitor fee is the only completed application for the IR process to DME. The glucose monitor IR purportedly took three years to complete. Yet, the time span from publication of the propose rule to the final rule only took one year (January 6, 1994 to January 17, 1995.) The other two years apparently were taken up by the "development" and "clearance" stages of the IR process. From the only completed, available example, the time delay appears to be in the development and clearance stages of the IR process. As stated earlier, the agency is not set up to collect and analyze data other than it own claims data.

To address the need for timely, comprehensive collection and analysis of comparative payment data, NAMES recommends that

Congress fund, and mandate HCFA to establish, a data collection system that includes ongoing monitoring and analysis of other DME payors across the country. By solving an inherent problem with HCFA's development and clearance process, Congress would successfully expedite the IR process without enacting an unclear, inflexible and arbitrary proposal.

Due to the sensitive and personal nature of services provided to consumers by the health care industry, it is essential that every provider be above reproach in the delivery of quality products and services. Legitimate HME providers, who comprise the vast majority of this small but growing home care industry, have a common interest with policymakers -- to stop all unethical HME business practices. This goal only can be achieved, however, through a comprehensive and targeted approach that supports legitimate providers by strengthening the HME services industry,

while also making it extremely tough on "scam" operations to conduct business.

NAMES recognizes the objective of Congress to improve the IR process. However, we submit that the problem with the process is inherent in HCFA's inability to continually track other payor sources throughout the year. Adding an arbitrary timeline to the IR process will only result in undermining the due process system. We can solve the inherent data problem by using preventive medicine to fund and mandate HCFA to establish a data collection system that includes ongoing monitoring and analysis of other payors across the country. Thank you. I would be glad to answer any questions.

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Statement
of the
National Association for Medical
Equipment Services
on
The Health Care Fraud and Abuse Prevention Act of 1996
H.R. 3224

Hearing of
Thursday, May 2, 1996

Before the
Committee on Government Reform and Oversight

Subcommittee on Human Resources and
Intergovernmental Relations

Subcommittee on Government Management,
Information & Technology

EXECUTIVE SUMMARY

NAMES, the only national association representing the home medical equipment (HME) services industry exclusively, is pleased to testify on H.R. 3224, the Health Care Fraud and Abuse Prevention Act of 1996. H.R. 3224 is an excellent step toward eradicating fraudulent providers from the health care system.

NAMES has worked diligently with Congress and the Administration to promote access to quality HME services and to help eliminate the few unethical providers who tarnish an otherwise upstanding, reputable industry. NAMES commitment to this effort is unwavering and we look forward to working with you to pass strict fraud and abuse legislation in 1996.

H.R. 3224 actively advocates for the eradication of fraudulent and abusive business practices in the health care industry. NAMES agrees with this goal.

By creating stiff fines and penalties for fraudulent and abusive health care providers, H.R. 3224 encourages ethical behavior and is consistent with the continuing trend of increasing both the criminal penalties and the number of criminal prosecutions with white collar crime. While supporting these provisions, NAMES feels that it is imperative to reach a good balance between education and strict enforcement. Education and guidance must be included for both consumers and providers.

Section 303 of H.R. 3224 requires the Department of Health and Human Services (HHS) to change a payment schedule for durable medical equipment (DME) "within one year after the HHS Secretary proposes an adjustment." NAMES submits that the language in Section 303 is, at best, vague and subject to a wide degree of interpretation. At worst, it severely jeopardizes the standard of due process.

If the intent of Section 303 is to implement a fee schedule change without regard to the findings of a complete and deliberative comparison of the available comparative payment data as required in the statute, then Section 303 should clearly state that intent.

If the intent of the amendment is to abrogate the requirements of the Administrative Procedures Act (APA) that public notice and comment occur **prior** to the implementation of the regulatory change, then the amendment should explicitly state that the APA requirements are being disregarded and/or clarify the exception of impracticality, lack of necessity or contrariness to the public interest on which the APA is being disregarded for the expediency of a payment change.

If the intent of the amendment is to speed the development and clearance processes of the inherent reasonableness IR process and substitute an interim final rule with comment for a proposed notice and comment, then the amendment is ambiguous and should be clarified.

Medicare law gives HCFA the general authority to make adjustments to Medicare fees when that fee is not "inherently reasonable by reason of its grossly excessive or grossly deficient amount" and to establish a fee "that is realistic and equitable." Comparison of the selected Medicare fee to other market prices plays a large role in the IR process but there is no magic formula for when a fee becomes "grossly excessive." This final determination is subjective. On the other hand, the statute and regulation are fairly specific about what factors must be considered by the agency. These factors were written with the specific intention of prohibiting HCFA from making arbitrary and hasty reductions.

When HCFA seeks to establish a specific dollar amount limit or special payment method, it must consider all "relevant data."

In determining the major difficulty in completing the developmental and clearance process, it is instructive to examine previous efforts. The most time-consuming stage can be traced to HCFA's inability to timely collect and analyze the relevant comparative payment data. The reason is clear. Unlike other federal agencies, HCFA's primary mission is not oversight and regulation of the industry, but the administration of a payment system for services and equipment provided to beneficiaries. Quite simply, the agency is not set up to collect and analyze data outside of that data that it generates itself, i.e., Medicare claims data.

The need to improve the IR authority should not dictate arbitrary deadlines that the agency is poorly structured to undertake. Faster does not necessarily mean better. Instead, the answer should include how to make HCFA a better, more efficient agency overall. The proposed amendment would require the publication of a payment adjustment action within one year. We remind the Committee that the adjustment to the glucose monitor fee is the **only** completed application of the IR process to DME. The glucose monitor IR purportedly took three years to complete. Yet, the time span from publication of the proposed rule to the final rule only took one year (January 6, 1994 to January 17, 1995.) The other two years apparently were taken up by the "development" and "clearance" stages of the IR process. From the only completed, available example, the time delay appears to be in the development and clearance stages of the IR process. As stated earlier, the agency is not set up to collect and analyze data other than its own claims data.

To address the need for timely, comprehensive collection and analysis of comparative payment data, NAMES recommends that Congress fund, and mandate HCFA to establish, a data collection system that includes **ongoing** monitoring and analysis of other DME payors across the country. By solving an inherent problem with HCFA's development and clearance process, Congress would successfully expedite the IR process without enacting an unclear, inflexible and arbitrary proposal.

Due to the sensitive and personal nature of services provided to consumers by the health care industry, it is essential that every provider be above reproach in the delivery of quality products and services. Legitimate HME providers, who comprise the vast majority of this small but growing home care industry, have a common interest with policymakers — to stop all unethical HME business practices. This goal only can be achieved, however, through a comprehensive and targeted approach that supports legitimate providers by strengthening the HME services industry, while also making it extremely tough on "scam" operations to conduct business.

NAMES recognizes the objective of Congress to improve the IR process. However, we submit that the problem with the process is inherent in HCFA's inability to continually track other payor sources throughout the year. Adding an arbitrary timeline to the IR process will only result in undermining the due process system. We can solve the inherent data problem by using preventive medicine to fund and mandate HCFA to establish a data collection system that includes ongoing monitoring and analysis of other payors across the country.



**Statement
of the
National Association for Medical
Equipment Services
on
The Health Care Fraud and Abuse Prevention Act of 1996
H.R. 3224**

**Hearing
of
Thursday, May 2, 1996**

**Before
the
Committee on Government Reform and Oversight
Subcommittee on Human Resources and Intergovernmental Relations
Subcommittee on Government Management, Information & Technology**

Mr. Chairman and Members of the Committee, my name is Rick Doherty. I have 16 years' experience as a provider of home medical equipment (HME) services. My company, Comprehensive Home Health Company, serves individuals residing in the metropolitan Boston area. I also serve on the Board of Directors and am a former Chair of the National Association for Medical Equipment Services (NAMES). I am pleased to testify today on behalf of HME services providers across the country and to address this

Committee on the Health Care Fraud and Abuse Prevention Act of 1996 (H.R. 3224) and the critical role that the HME services industry plays in helping to eliminate fraud and abuse in our nation's health care delivery system.

NAMES members comprise over 1,600 HME companies which provide quality, cost-effective HME services and rehabilitation/assistive technology to consumers in their homes. According to physician prescription, HME providers furnish an extremely wide array of HME and related services to consumers ranging from more "traditional" HME items such as standard wheelchairs and hospital beds, to highly advanced services such as oxygen therapy, nutrition and intravenous antibiotic therapies; apnea monitors and ventilators; and specialized rehabilitation equipment such as wheelchairs, customized for the unique needs of people with disabilities. Many of these consumers are Medicare beneficiaries.

Mr. Chairman, NAMES applauds your continued efforts to fight health care fraud and abuse. H.R. 3224, sponsored by you and Mr. Schiff (R-NM), is an excellent step toward eradicating fraudulent providers from the health care system. NAMES has worked diligently with Congress and the Administration to promote access to quality HME services and to help eliminate the few unethical providers who tarnish an otherwise upstanding, reputable industry. NAMES commitment to this effort is unwavering and we look forward to working with you to pass strict fraud and abuse legislation in 1996.

HME Services Industry Efforts to Eradicate Fraud and Abuse

In 1995, NAMES founded, and continues to chair, the Coalition of Health Associations United Against Fraud and Abuse, which is working closely with Congress and the Administration to find a legislative solution to fight health care fraud. Together with the Coalition, NAMES presented Congress with its Anti-Fraud and Abuse Proposal (Attachment 1), much of which has been crafted into legislation, S. 1028, the Health Insurance Reform Act which passed the Senate last week, as well as the Health Care Availability and Affordability Act of 1996 (H.R. 3160) which passed the House on March 28, 1996, and contains provisions similar to H.R. 3224. We have worked on a bipartisan basis whenever we can to improve efforts against fraud and abuse.

NAMES legislative proposals designed to reduce fraud and abuse include: establishing a health care fraud statute in the Criminal Code; excluding fraudulent providers from federal and state health care programs; clarifying anti-kickback laws; and improving the efficiency of the Medicare claims process through the use of newer technology to increase detection of improper billing.

In addition to assisting in the development of strong ethics legislation, NAMES conducts an aggressive effort to educate consumers about fraud and abuse in the HME services industry and to identify the proper channels for reporting potentially abusive practices. NAMES members also encourage all concerned beneficiaries to use the OIG fraud hotline number and provides a list of the Federal Bureau of Investigation (FBI) Health Care Fraud Unit offices. We have worked with the OIG, FBI and other federal agencies to appropriately address fraud and abuse.

NAMES members are subject to strict guidelines as outlined in the Association's Code of Ethics (established in 1987) and Guide for Conduct (established in 1991) (Attachment 2). Member companies are encouraged to take an active role in preventing and reporting fraud and abuse, as well as complying with the Health Care Financing Administration (HCFA) and the Office of Inspector General (OIG) regulations. Questionable practices are reviewed by NAMES Ethics Committee. In accordance with NAMES bylaws, membership may also be terminated when violations occur.

NAMES efforts are long-term in nature but have had a positive effect in Congress and the Administration. NAMES members have long been recognized as representing the most ethical component of the HME industry and have been noted for taking a courageous stand to rid the HME services industry of abusive business practices.

The Health Care Fraud and Abuse Prevention Act of 1996

Mr. Chairman, H.R. 3224 actively advocates for the eradication of fraudulent and abusive business practices in the health care industry. NAMES agrees with this goal.

NAMES strongly supports:

- Setting specific and significant federal penalties for perpetrating fraud against any health care program;
- Requiring federal enforcement authorities to coordinate their efforts more effectively;
- Defining public and private health care fraud as a federal crime while establishing stiff fines and imprisonment;
- Limiting health care providers to one universal billing number;
- Raising the qualification requirements for those providers seeking a billing number; and
- Expanding the exclusion authority in order to debar providers who consistently abuse the system.

By creating stiff fines and penalties for fraudulent and abusive health care providers, H.R. 3224 encourages ethical behavior and is consistent with the continuing trend of increasing both the criminal penalties and the number of criminal prosecutions with white collar crime. While supporting these provisions, NAMES feels that it is imperative to reach a good balance between education and strict enforcement. Education and guidance must be included for both consumers and providers. In this regard we recommend:

- Establishing a control account to help defray federal and state costs of prevention and detection, which H.R. 3224 proposes. However, the account should be used to cover costs of the program with no less than 20% earmarked for provider and consumer education regarding compliance. The control account also should be subject to the Congressional appropriations process to contain the "bounty hunter" mentality;
- Supporting guidance regarding application of health care fraud and abuse sanctions by requiring the HHS to issue advisory opinions. This provision was included in the recently passed House Bill H.R. 3160; and
- Supporting the clarification of the level of intent required for imposition of sanctions, also included in H.R. 3160.

The Inherent Reasonableness Process

Title III of H.R. 3224 requires the Department of Health and Human Services (HHS) to adopt market sensitive, competitive and prompt pricing of equipment and services to avoid overpayment of claims made by health care providers. Section 303 of the bill would require HHS to change a payment schedule for durable medical equipment (DME) "within one year after the HHS Secretary proposes an adjustment." This fee schedule payment change would be issued as an interim final rule under the "inherent reasonableness" authority of the Secretary of HHS.

The inherent reasonableness (IR) process is used by the Secretary of HHS to determine if a Medicare payment amount "is not inherently reasonable by reason of its grossly excessive or grossly deficient amount." (§1842(b)(8)(A)(i) of the Social Security Act.) When passed by Congress in 1985, the IR process applied to physician payment amounts. In 1987, Congress passed §1834(a) of the Social Security Act, establishing a series of fee schedule payment methodologies for DME. The IR process of §1842(b)(8) and (9) was directly incorporated by reference in §1834(a)(10)(B) as being directly available to the Secretary of HHS for use with DME fee schedule payment amounts. Section 303 of H.R. 3224 would amend §1834(a)(10)(B).

Mr. Chairman, NAMES submits that the language in Section 303 is, at best, vague and subject to a wide degree of interpretation. At worst, it severely jeopardizes the standard of due process. If the intent of Section 303 is to implement a fee schedule change without regard to the findings of a complete and deliberative comparison of the available comparative payment data as required in the statute, then Section 303 should clearly state that intent.

If the intent of the amendment is to abrogate the requirements of the Administrative Procedures Act (APA) that public notice and comment occur **prior** to the implementation of the regulatory change, then the amendment should explicitly state that the APA requirements are being disregarded and/or clarify the exception of impracticality, lack of necessity or contrariness to the public interest on which the APA is being disregarded for the expediency of a payment change.

If the intent of the amendment is to speed the development and clearance processes of the inherent reasonableness process and substitute an interim final rule with comment for a proposed notice and comment, then the amendment is ambiguous and should be clarified. (HCFA's IR process is illustrated in Attachment 3.)

Medicare law gives HCFA the general authority to make adjustments to Medicare fees when that fee is not "inherently reasonable by reason of its grossly excessive or grossly deficient amount" and to establish a fee "that is realistic and equitable." Comparison of the selected Medicare fee to other market prices plays a large role in the IR process but there is no magic formula for when a fee becomes "grossly excessive." This final determination is subjective. On the other hand, the statute and regulation are fairly specific about what factors must be considered by the agency. These factors were written with the specific intention of prohibiting HCFA from making arbitrary, fast, reductions.

The House Report accompanying H.R. 3128, the "Deficit Reduction Amendments of 1985" (House Rpt. 99-241, Part 1), states that:

The requirement for promulgation of such regulations is intended to prevent arbitrary application of inherent reasonableness and to expose to public comment the process and criteria to be used. (Id.)

The House Report further adds that:

In order to prevent arbitrary application of the "inherent reasonableness" clause (already in regulations), the Secretary would be required to promulgate regulations which specify explicitly the criteria of "inherent reasonableness." (Id.)

In addition, on April 24, 1986, Senator Lloyd Bentsen (D-TX), then member of the Senate Finance Committee, noted during Senate debate on related legislation (S. 2368, the "Physician Payment Reform Act of 1986") that the provision requires that:

[I]n defining inherent reasonableness, the Administration [must] consult with the Physician Payment Assessment Commission to ensure that increases or decreases in the pricing of services are undertaken only after the potential effect on the quality of care is evaluated. To preclude hasty adoption of changes in reimbursement policy, the Secretary of HHS would be required to follow formal rulemaking procedures, including a 60-day public comment period. (132 Cong. Rec. at S. 4856.)

Furthermore, at an April 25, 1986 hearing on "Proposals To Modify Medicare's Physician Payment System," then-Senate Finance Subcommittee on Health Chairman David Durenberger (R-MN) noted that:

Our bill, S. 2369, will take the Administration's authority to reduce fees and force that authority to respond to a process which would be laid out in the law. That process will guarantee that fee revisions are made on the basis of sound information which is available for public review and comment, and that fee revisions are made only after the comments of Medicare beneficiaries, physicians, and the new Physician Payment Review Commission have been received and considered. (S. Hrg. 99-727 at 63.)

When HCFA seeks to establish a specific dollar amount limit or special payment method, it must consider all "relevant data."

In determining the major difficulty in completing the developmental and clearance process it is instructive to examine previous efforts. The most time-consuming stage can be traced to HCFA's inability to timely collect and analyze the relevant comparative payment data. The reason is clear. Unlike other federal agencies, HCFA's primary mission is not oversight and regulation of the industry, but the administration of a payment system for services and equipment provided to beneficiaries. Quite simply, the agency is not set up to collect and analyze data outside of that data that it generates itself, i.e., Medicare claims data.

Mr. Chairman, you specifically asked NAMES to address the need to improve the process by which HHS exercises its inherent reasonableness authority. The GAO reported to you in their September, 1995 report, "Medicare Spending: Modern Management Strategies Needed to Curb Billions in Unnecessary Payments," on page 9:

"A HCFA official explained that HCFA lacked resources to deal with questions of reasonable pricing for more than one item at a time, though the agency would like to compare prices for about 80 of the supplies and services that are most costly overall."

Furthermore, on page 11 of the same report, GAO states:

"Despite HCFA's awareness of weaknesses in its controls over payment of claims — the program's chief administrative function — its enhancement of these controls is problematic. In the current fiscal environment, resources are particularly scarce. In addition, Medicare's existing computer systems and related software for processing and paying claims do not adequately detect Medicare billing abuses."

The need to improve the IR authority should not dictate arbitrary deadlines that the agency is poorly structured to undertake. Faster does not necessarily mean better. Instead, the answer should include how to make HCFA a better, more efficient agency overall. The proposed amendment would require the publication of a payment adjustment action within one year. We remind the Committee that the adjustment to the glucose monitor fee is the **only** completed application of the IR process to DME. The glucose monitor IR purportedly took three years to complete. Yet the time span from publication of the proposed rule to the final rule only took one year (January 6, 1994 to January 17, 1995.) The other two years apparently were taken up by the "development" and "clearance" stages of the IR process. From the only completed, available example, the time delay appears to be in the development and clearance stages of the IR process. As stated earlier, the agency is not set up to collect and analyze data other than its own claims data.

To address the need for timely, comprehensive collection and analysis of comparative payment data, **NAMES recommends that Congress fund, and mandate HCFA to establish, a data collection system that includes ongoing monitoring and analysis of other DME payors across the country.** By solving an inherent problem with HCFA's development and clearance process, Congress would successfully expedite the IR process without enacting an unclear, inflexible and arbitrary proposal.

Specific Recommendations for the HME Services Industry

NAMES has repeatedly apprised HCFA of problem areas that exist within the HME services industry. Mr. Chairman, we have asked for assistance and guidance in controlling fraud and abuse. No one can deny that real problems have been promulgated by the loopholes that exist within HCFA. By closing these loopholes, Congress and HCFA could take a significant step to reduce the need to even begin the IR process. We urge Congress and the Administration to work with our industry to close these loopholes and rid our industry of those who engage in fraudulent activities.

Recently, NAMES took a serious look at specific fraudulent problem areas with the provision of HME services and rehab/assistive technology in the Medicare program. The following reflects our proposed solutions to those problems which we believe will potentially save the Medicare program millions of dollars.

- **Accountability Measures — The Need for Standards.** NAMES has advocated for years that there must be stronger accreditation, certification and licensure requirements, including on-site inspections. Despite the work of NAMES and HME providers to create a higher level of service for individuals in need of care, formal Medicare certification standards for the provision of HME services still do not exist today. HCFA has no detailed requirements for beneficiaries receiving HME services. There are no provisions regarding type or frequency of services that should be rendered; record-keeping practices; emergency care; patient education; home safety assessments; or infection control practices.
- **Consistent Monitoring of the HCFA Common Procedure Coding System (HCPCS) Codes.** The HCPCS codes are currently updated on a yearly basis only. One of the possible abusive areas in HME is questionable coding practices. By legislatively mandating HCFA to evaluate the coding system quarterly, Congress could eliminate problems that have occurred in similar situations with support surfaces.

NAMES also would advocate that Congress create a **Manufacturer and Provider Advisory Committee** to assist HCFA in setting the HCPCS Codes and to recommend appropriate descriptors to help identify emerging technology.

- **Optional Electronic Preauthorization.** Assistive technology and special wheelchair systems require billing and delivery prior to claims submittal. HCFA has no set time period for claim adjudicating and guaranteed payment. We have received information which suggests that some providers may be submitting claims and paperwork indicating that the equipment has been delivered, when in fact they have not even begun constructing the equipment. Providers will do this in order to get advanced assurance of Medicare coverage and payment for costly, complex equipment that has been prescribed by the physician.

By requiring HCFA to set up an optional 5-day response electronic preauthorization system for rehab/assistive technology for equipment costing over \$1,000, Congress could deter any incentives to engage in this practice by reassuring the provider that their services will not go unpaid.

- **Equipment Upgrades.** Currently, a Medicare beneficiary with a prescription who wishes to purchase certain pieces of equipment may be unable to do so. For instance, a beneficiary who has a prescription for a full-electric hospital bed to meet their physical needs is prohibited by Medicare to purchase the bed. Although Medicare will pay for the rental of a semi-electric bed, a full-electric bed is deemed medically unnecessary, even as originally prescribed by the physician. In essence, regardless of the patient's medical needs or a physician's prescription, Medicare makes the final medical need and payment decisions.

When a beneficiary needs an item of medical equipment, the providers will bill Medicare for the item and Medicare may deny payment and instead substitute another item that costs Medicare less. In addition,

Medicare denies the beneficiary the ability to “upgrade” to their equipment of choice. NAMES supports legislative efforts to allow equipment upgrades for Medicare beneficiaries with no increase in Medicare outlays. This provision was passed by the House and the Senate in their respective budget bills last year, but was taken out due to a technical procedure.

Conclusion

Due to the sensitive and personal nature of services provided to consumers by the health care industry, it is essential that every provider be above reproach in the delivery of quality products and services.

Legitimate HME providers, who comprise the vast majority of this small but growing home care industry, have a common interest with policymakers — to stop all unethical HME business practices. This goal only can be achieved, however, through a comprehensive and targeted approach that supports legitimate providers by strengthening the HME services industry while also making it extremely tough on “scam” operations to conduct business.

NAMES commends the efforts of this Committee. However, NAMES strongly believes that, in order to achieve the most effective and highest quality of care for consumers, we must balance provider and consumer education with punishment and also protect the interests of providers who attempt to honestly stay within complex laws in a changing health care environment.

NAMES recognizes the objective of Congress to improve the IR process. However, we submit that the problem with the process is inherent in HCFA’s inability to continually track other payor sources throughout the year. Adding an arbitrary timeline to the IR process will only result in undermining the due process system. We can solve the inherent data problem by using preventive medicine and health to fund and mandate HCFA to establish a data collection system that includes ongoing monitoring and analysis of other payors across this country.

We look forward to working with you, your Committee and your staff on passage of strict fraud legislation this year. Thank you.



NAMES

National Association for
Medical Equipment Services

Attachment 1

The Coalition of Health Associations United Against Fraud and Abuse

Coalition
of Health
Associations
United
Against
Fraud
and
Abuse

The Coalition is made up of organizations that represent health care providers and suppliers who want to work with Congress and the Administration to help eliminate fraud and abuse.

The Coalition believes that existing fraud and abuse statutes must:

- Increase tools of enforcement against willful and criminal violations by giving regulators budgetary recognition and sufficient resources to enforce the law;
 - Provide adequate and thorough education for providers, consumers, and payers to prevent violations;
 - Protect Federal health care programs from unnecessary cost, utilization, and the failure to deliver appropriate levels of care;
 - Be appropriate for the changing health care market; and
- Separate willful from technical violations.

The Coalition further urges Congress to adopt the following proposals to help eliminate health care fraud and abuse.

I. Tools of Enforcement

Federal Regulators should have the ability to prosecute fraudulent health care providers and suppliers.

- A. **Establish a new health care fraud statute in the criminal code.** Providing penalties of up to ten years in prison, or fines, or both for willfully and knowingly executing a scheme to defraud a health plan in connection with the delivery of health care benefits, as well as for obtaining money or property under false pretenses from a health plan will help as a deterrent to fraud.
- B. **Provide for the creation of an Anti-fraud and Abuse Collection Account.** An account subject to the congressional appropriations process will provide the Office of the Inspector General and the Federal Bureau of Investigation with the resources necessary to prosecute fraudulent providers and suppliers, and to provide guidance to those who seek to comply with the law.
- C. **Clarify Antikickback Statute.** The current antikickback statute is vague and not focused on fraudulent activity. This provision would ensure that the antikickback law applies to those who intentionally defraud the government by codifying the Hanlester Network VS. Shalala decision. In this case, the court ruled that "knowingly and willfully" committing a fraudulent act should be the basis of federal prosecution. In addition, there is a clarification to the longstanding issue that an action is illegal, if a "significant or substantial reason" for making a payment is to induce referrals.
- D. **Additional Enforcement Tools.** In addition to criminal prosecution, regulators are given the following enforcement tools to punish those found to commit a health care fraud offense:

1. **Exclusion from Federal and State Health Care Programs.** Mandatory exclusion from Medicare and state health care programs to those convicted of a health care felony. Increase existing permissive exclusion and apply it to an officer in an entity that has been convicted of a health care offense, if that officer is found to have a "reason to know" that the crime was committed; and
2. **Expansion and increase in civil monetary penalties.** Expanding penalties will serve as an appropriate deterrent.

II. Health Care Fraud and Abuse Guidance

It is the belief of the coalition that the vast majority of providers and suppliers seek to comply with the complex laws of Medicare and Medicaid. We further believe that much of the "noncompliance" can be resolved with education and guidance. The following provides mechanisms for further guidance to health care providers on the scope and applicability of the anti-fraud statutes.

- A. **Safe Harbors.** Updates existing safe harbors and creates new ones.
- B. **Fraud Alerts.** Establishes a formal process for the request and issuance of special fraud alerts.
- C. **Advisory Opinions.** Advisory opinions assist providers and others engaged in the delivery of health care to ensure that they remain in compliance with health care statutes and regulations.

III. Medicare Claims Process

The General Accounting Office (GAO) in its report entitled "Medicare Claims - Commercial Technology Could Save Billions Lost to Billing Abuse" (May 1995) stated "Flawed payment policies, weak billing controls, and inconsistent program management have all contributed to Medicare's vulnerability to waste, fraud, and abuse." The following provisions will improve that process.

- A. **Medicare Transaction System (MTS).** Downgrade the priority or terminate the development of the Medicare Transaction System.
- B. **Commercial Automatic Data Processing Equipment (ADPE).** Require Medicare carriers to acquire commercially made Commercial Automatic Data Processing Equipment.
- C. **Reduce number of Medicare Carriers to ten.** Upon implementation of the ADPE, HCFA should be required to study and report to Congress on reducing its 32 Medicare Part B carriers to 10 such as the Durable Medical Equipment Regional Carriers (DMERCs) that were reduced to four. This will help to foster better communication between HCFA and the Regional Carriers.
- D. **Contractor/Provider Relationships.** Prohibit Medicare carriers and intermediaries from reviewing claims of provider organizations when the Medicare contractor has an investment in that organization;
- E. **Study Fraud and Abuse Under Managed Care.** The rise in managed care brings new forms of fraud and abuse. For example, the government and beneficiaries may be defrauded through withholding necessary services. The Institute of Medicine should undertake a study on the types of fraud that it may encounter under managed care and to begin ways to detect and combat such fraud.



NAMES

National Association for
Medical Equipment Services

Attachment 2

NAMES Code of Ethics



Code of Ethics

Having been accepted into membership in the National Association for Medical Equipment Services (NAMES), we do hereby subscribe without reservation to the Association's Code of Ethics.

The purpose of the Code of Ethics shall be to set and improve standards within the practice of providing home medical equipment and services. To maintain the ethical conduct and integrity of this Association, a NAMES member pledges to abide by the following:

1. To render the highest level of care promptly and competently taking into account the health and safety of the patient.
2. To serve all patients regardless of race, creed, national origin or reason of illness.
3. To provide quality home medical equipment and services which are appropriate for the patients' needs.
4. To instruct the patients and/or caregivers in the proper use of the equipment.
5. To explain fully and accurately to patients and/or caregivers patients' rights and obligations regarding the rental, sale and service of home medical equipment.
6. To respect the confidential nature of the patients' records and not to disclose such information without proper authorization, except as required by law.
7. To continue to expand and improve professional knowledge and skills so as to provide patients with equipment and services which are continually updated.
8. To abide by both Federal and local laws and regulations which govern the home medical equipment services industry.
9. To avoid participating, directly or indirectly, with a source of patient referrals in a "captive referral arrangement"; whereby patients are directed to utilize a supplier of home medical equipment in derogation of the patients' right to select the suppliers of their choice.
10. To act in good faith; to be honest, truthful and fair to all concerned.



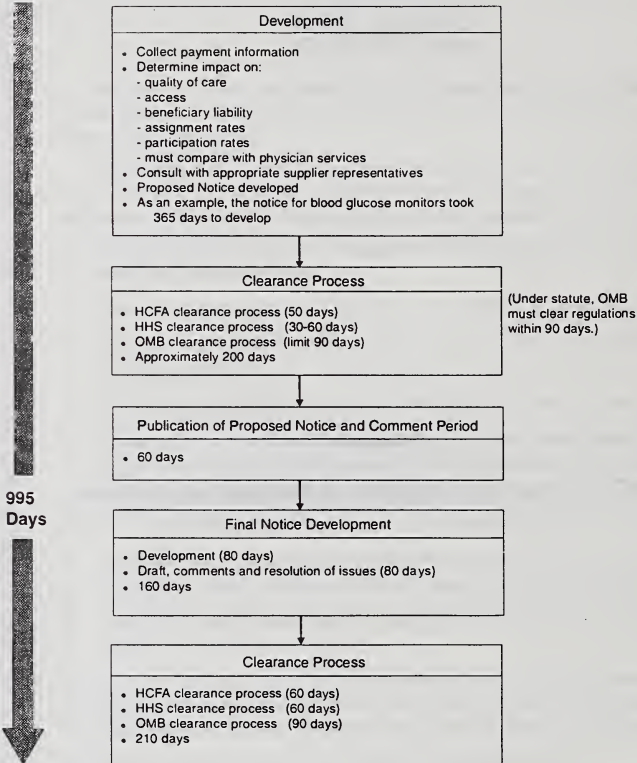
NAMES

National Association for
Medical Equipment Services

Attachment 3

HCFA's Process for Using Inherent Reasonableness Authority

Figure 1: HCFA's Process for Using Inherent Reasonableness Authority



Mr. SHAYS. Thank you. I thank both gentlemen.

Let me say this to you. You are here representing the industry. I want to show you a lot of courtesy in this. I don't want to cross the line of seeming to be impatient. But—and the “but” is this—it just seems to me like both testimonies are arguing in two different directions to protect what exists today. And what exists today is a process to adjust prices that basically takes well over 2 years. Two years is the fast track.

Now, is it the testimony of both of you that you think there should be less Government regulation or more Government regulation?

Mr. FOREMAN. I would suggest that there should be less Government regulation. And my feeling is this, that there should not be an adversarial relationship between HCFA and the industry.

Mr. SHAYS. If you don't mind, I'll just take the questions. But I'm going to give you the chance to make every point you want to make.

Mr. Doherty.

Mr. DOHERTY. We certainly support less Government regulation.

Mr. SHAYS. OK. So your positions start with this. you don't want more regulation; you want less regulation. Would you agree that it is stupid for the Government to pay more than the market rate?

Mr. DOHERTY. Yes.

Mr. FOREMAN. You can't dispute that. No; of course not.

Mr. SHAYS. OK. Do you agree that a process that takes 3 years means that sometimes the Government is paying more than the market rate?

Mr. FOREMAN. Possibly.

Mr. SHAYS. Not “possibly.” You're too smart a man. Possibly? Is it? Has it sometimes paid more?

Mr. FOREMAN. It has at times, yes.

Mr. DOHERTY. There's only one example in our industry, Mr. Chairman, where the process has been carried through, and that's the glucose monitor.

Mr. SHAYS. Mr. Doherty, I didn't ask that question. I'll give you a chance. I asked, do you think that there are examples where the Government pays more than the market rate?

Mr. DOHERTY. There probably are a few examples.

Mr. SHAYS. No, no, no. No, not “probably.” Do you really think “probably,” or do you think there are? I'm going to be honest with you. I want you to be honest with me.

Mr. DOHERTY. I think there are a few.

Mr. SHAYS. Only a few?

Mr. DOHERTY. Yes.

Mr. SHAYS. OK. First off, what does “not grossly excessive” mean? “Grossly,” what does that mean, that term? What is “grossly excessive”?

Mr. DOHERTY. You're asking for my opinion of what it means?

Mr. SHAYS. Well, it's the law. It's what you want me to keep. I mean, I hope to God we know what it means. I hope you know what it means, because that's the law; that's what you're under.

Mr. DOHERTY. Well, it's the law. It's subject to interpretation.

Mr. SHAYS. Right. What does it mean?

Mr. DOHERTY. My assumption is that it means that, looking at the entire market and in the entire realm of payers and what's being paid, that Medicare is not paying a fee that is grossly above the next-closest fee.

Mr. SHAYS. What's your term?

Mr. FOREMAN. I would say that it's an obscene rate. Is the discussion that you're saying, are there products?

Mr. SHAYS. No, no, no, no. I don't want you to say what I'm saying. I want to know what you know. I want to know what "grossly excessive" means. I think this is gross. I want to know what you think "grossly excessive" means. That's what the law is. That's what the industry wants to maintain, "grossly excessive." So what does it mean?

Mr. Foreman.

Mr. FOREMAN. I would say it's obscene profit above the total cost to provide that product. That includes not only the cost of the product but also the services that are provided.

Mr. SHAYS. So "grossly excessive" means "obscene." What is "obscene"? How do you define "obscene"?

Mr. FOREMAN. Well, an excessive price would be that it happens to be at the highest rate that is charged to the marketplace. That could be considered excessive.

Mr. SHAYS. We're qualifying "excessive." We're saying not "excessive"—I mean, that would be an improvement. That would be an improvement. I mean, if I went to my constituents and I said, well, we have devised a system in the Federal Government where the marketplace can, in fact, charge "grossly excessive" until we go through a 2- to 3-year process of getting it to be not "grossly excessive," they would say that's pretty stupid.

If I went to them and I said, we have a system that says they can charge "excessive," not "grossly excessive," just "excessive," they, my constituents, would say that's pretty stupid and foolish. And they would say it's their dollars and why are you wasting them?

Why should vendors be able to charge "excessive"? I'm forgetting "grossly excessive." Why should they be allowed to charge excessive rates?

Mr. DOHERTY. Nobody should be allowed to charge excessive rates, Mr. Chairman. But until the rate is determined to be excessive.

Mr. SHAYS. OK. We'll work on that, but that's not even the definition we're using.

Mr. Foreman.

Mr. FOREMAN. Rates—of course, we're using an adjective here. It's in the eyes of the beholder what is considered excessive, what is considered grossly excessive.

Mr. SHAYS. Well, if it was in the eyes of the beholder, it shouldn't be in the statute. It has a term of art that protects you and is supposed to protect the taxpayers. So I need to know what "grossly excessive" is. You basically have told me "grossly excessive" is obscene, and I would agree that that is obscene.

So I am assuming that, if it's not obscene but very excessive, then you vendors are allowed to charge that rate. And so then I come to this point, and I try to say, should vendors be allowed to

charge excessive rates? Let's take "grossly" out of there and "obscene" out of there.

Mr. DOHERTY. I think there is a problem.

Mr. SHAYS. I'm going to ask this question, and I'm going to want an answer. Should vendors be allowed to charge excessive rates?

Mr. FOREMAN. Yes.

Mr. SHAYS. What is your answer, Mr. Doherty?

Mr. DOHERTY. With my interpretation of the word "excessive," no. But the market has to determine what a fair market price is.

Mr. SHAYS. But we don't have the word "fair." If we had the word "fair," if we had the word "market price," anytime it was above the market price—but we don't say that. We have "grossly excessive." So if it's less than "grossly excessive," then, under this regulation, we can't change the rate. And, in fact, if it's "excessive," we can't change the rate, because we allow "grossly excessive."

In fact, if we just took "grossly" out, we would still have "excessive," and that's wrong. You told me, Mr. Foreman, it's not wrong. You're telling me it is all right for vendors to charge an excessive rate.

Mr. FOREMAN. And I explained why.

Mr. SHAYS. Yes.

Mr. FOREMAN. One of the things that was discussed here was the fact that Medicare is the largest buyer of durable medical equipment in the country. Therefore, why are they paying more than, say, some other buyers. Let me say this, that Medicare and HCFA don't buy a thing. They pay for the product.

Mr. SHAYS. Hold on. Who pays for the product?

Mr. FOREMAN. Medicare pays for the product. The Government. I pay for the product.

Mr. SHAYS. You pay for the product.

Mr. FOREMAN. I pay for the product.

Mr. SHAYS. You pay for the product, and I pay, and everybody else pays.

Mr. FOREMAN. What happens here is that every single sale or every single buy is not made by HCFA, is not made by the government; it's made by a third party. We, as an industry, then will have to accumulate enough information and be able to provide that information to HCFA on notice or as we're audited. Let's say we are ethical organizations here and we will provide those documents.

Mr. SHAYS. I want to be cooperative here. I just want to know where you're headed. What's your point? What's the bottom line?

Mr. FOREMAN. Well, what I'm saying is that we are required to provide more services and more administrative activity to sell the same product to a Medicare patient than we would have if we were selling to a hospital or we were selling to, say, a nursing agency.

Mr. SHAYS. Because?

Mr. FOREMAN. Because they buy in bulk.

Mr. SHAYS. Wait a second. When you buy in bulk you have an advantage and if you are selling in bulk.

Mr. FOREMAN. That's right.

Mr. SHAYS. OK. So, I mean, I'm sorry, I don't know why selling in bulk puts you at a disadvantage. It puts you at an advantage.

Mr. FOREMAN. It puts me at an advantage, if I was selling in bulk.

Mr. SHAYS. Yes.

Mr. FOREMAN. But I don't sell in bulk to Medicare patients. I sell products individually to Medicare patients. Every patient, whether it's a \$12 charge or whether it happens to be a charge for oxygen or a bed, takes the same amount of paperwork, the same amount of services, as if someone walked into the store and bought it themselves and we had to go through the whole process.

Mr. SHAYS. Let me just say this to you. I agree that whatever you have to go through, whatever process, you compare apples to apples. That is a fair comment. But that wasn't an answer to my question. That was a very good statement which I agree with. And to be fair to you, we have to make sure that we compare apples to apples.

But my question to you was, you made the point that the industry should be allowed to charge not just "grossly excessive," because we agree that "obscene" or "grossly" shouldn't be, but you agreed that it should be allowed to charge an "excessive" rate.

Mr. FOREMAN. An excessive rate can also be interpreted as higher than the average rate, or higher than the lowest rate is an excessive charge. When you asked me can we charge an excessive rate, I say, yes, if you happen to interpret "excessive" to mean higher than, say, a normal charge.

Mr. SHAYS. Mr. Doherty.

Mr. DOHERTY. I think, Mr. Chairman, we're getting into semantics a little bit.

Mr. SHAYS. Could I say something? No, we're not getting into semantics. We're getting into what is the law. The law is what you're arguing to keep, and it says "grossly excessive," and that's not semantics to me.

Mr. DOHERTY. We're not necessarily arguing, Mr. Chairman, to keep that language. We have no control over the language in the statute.

Mr. SHAYS. No, no, no, no. You are arguing to keep the law the way it is.

Mr. DOHERTY. We're arguing to keep the due process the way it is.

Mr. SHAYS. OK. So due process you are arguing for. You would suggest, then, that we should change the law?

Mr. DOHERTY. I would suggest that we have no quarrel with anything that you would do to expedite the process, provided the due process part of it remains intact.

Mr. SHAYS. OK. Expedite the process. That's fair, that you want a due process system. I mean, that's fair for you to argue. But is your testimony that we could change the word, instead of say "grossly excessive," we could take out "grossly"? That would be acceptable to you?

Mr. FOREMAN. Yes, it would.

Mr. SHAYS. Would it be acceptable to you to take out the word "excessive" and replace it with "market rate"?

Mr. DOHERTY. I think that the word "excessive" or the term "grossly excessive" are both just open to too much interpretation, and they should be better defined.

Mr. SHAYS. OK.

Mr. DOHERTY. In answer to your question, I don't believe that Medicare should pay an excessive amount, but I obviously have a different interpretation of the word "excessive" than my counterpart here testifying. So the problem is in the language of the statute not being defined properly. If you ask 10 people, you might get 10 different explanations of what "grossly excessive" is.

Mr. SHAYS. I happen to take the view that the Government, the taxpayers shouldn't pay more than others pay for a product. I happen to agree with you that we should have less regulation rather than more. I'm very willing to get rid of the entire regulation.

I'm very willing to have the Federal Government say, "This is the price we're willing to pay, if you are willing, as a vendor, to provide to the service and do it." If you, as a vendor, are not willing to provide the service, then don't do it. So I'm going to go to my very conservative colleagues, who want to get rid of regulations, and say to them, "Why do we have that regulation? You think we have too much regulation. Why do we have it?"

Now, there may be an argument. We're going to hear it. But it's just disingenuous, frankly, to hear your first comment in your testimony. I was almost going to interrupt you. To talk about how you want less regulation and then say a system that allows the taxpayer, a year into the process, to have a price that is an interim price is more regulation, to me, is an absurdity.

If, in fact, we're going to get in a debate about regulation, then you're going to win the debate. And I'm going to go to the Speaker and say, "Mr. Speaker, you don't like regulation; I don't like regulation. I know how we can get rid of a lot of regulation. And the industry should support it, because we're going to get rid of regulation." I don't mean to be cute here, but that's kind of how I'm beginning to feel.

I mean, it's just disingenuous, from my standpoint. Now, if your comment that if you do have a due process system—this process isn't fair and there's a way to do it better, that's a fair debate, and we can have an honest debate about that.

I happen to believe that it is wrong to pay more than the market rates. It's clearly wrong to pay "grossly excessive," clearly wrong to pay "excessive," and it should be at the market rate, comparing apples to apples. If it's individuals to individuals, it should be the price that an individual pays. But if an individual can buy certain products at less than what we pay, then I have a problem with our paying more.

Mr. DOHERTY. We have a problem, Mr. Chairman. We agree with what you're stating; we have a problem with HCFA being able to determine what the market rate is. History has shown us that they have an unwillingness to be confused by the facts.

Mr. SHAYS. There we do agree. Sometimes.

Mr. DOHERTY. Their comparison of the VA Administration's payments for oxygen with the Medicare fees, it's totally apples and oranges. Again, they are reluctant to look at the facts and make a good determination.

Mr. SHAYS. Your argument would be that, in one case, it is a collective payment—well, that you provide more in bulk to the VA hospital, and to Medicare it's individual, in terms of the oxygen.

Mr. FOREMAN. That's a small part of the argument.

Mr. SHAYS. Plus, more services.

Mr. FOREMAN. That's right.

Mr. DOHERTY. There are more services. There's also a billing process that's totally different. Medicare pays under a whole different modality than the VA system does. So what HCFA states is that the VA pays a smaller amount to rent an oxygen concentrator, and that's true. What they don't go on to state is that the VA pays separately for all the other items that are included in the Medicare reimbursement.

Mr. SHAYS. Well, we're going to ask the Inspector General to go back over that issue, because I think it's valid, to a point. But if, in fact, over a 5-year period, the Federal Government pays \$4 billion more for these oxygen concentrators, if, in fact, it is \$5 billion more, and you say we're comparing apples to oranges, maybe it isn't \$5 billion—excuse me, over a 5-year period, \$4 billion more—excuse me, \$4 billion more.

Maybe they are wrong by half. Maybe it's \$2 billion. Maybe they are wrong by three-quarters. That's something that I'm going to ask for a comment on from the Inspector General before they leave, just so I can define that challenge. Then we're going to go back and ask them to pursue that, because it's a valid point. We've got to be fair to the industry. We've got to compare apples to apples and oranges to oranges, services to services, size to size, and so on.

I really believe we're going to change this system. I have a hard time understanding—and this will relate to this last question—if we have a process that basically takes about 3 years to change a price, if the price is too low and it's much less than your cost, are you forced to sell it to the Government?

Mr. FOREMAN. We are not forced to sell it, but we don't have to sell it. And it will come out that we won't sell it, except for one thing, the marketplace—I'm not talking about Medicare; I'm talking about the people that actually buy the product—may insist that we provide that product to a Medicare patient. The reason for it is that they won't give us any other business.

Mr. SHAYS. OK. Well, let me just say this to you. Your answer is very instructive, because you got it on one side and not on the other side. The bottom line is, if the price is too high, you are a willing seller, and if the price is not high, you don't have to sell. You may, in some instances, but you don't have to sell.

So you have the market price concept protecting you from selling when you are at a loss, and you have regulation protecting you when you get, frankly, close to or more than an obscene profit, or an excessive profit, or grossly excessive. So if we're going to be fair about comparing apples to apples, I want the same system to work fairly for both sides. It doesn't work fairly for the taxpayer, in my judgment.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Mr. Doherty, generally, I agree with your point that our enforcement efforts should be balanced by sufficient education and guidance. You make a point of that. However, I was under the impression that providers do, in fact, receive clear guidance from HCFA about Medicare and Medicaid requirements. Is that true?

Mr. DOHERTY. In many cases, it's true. There are also instances where the regulations and fee schedules are ambiguous to the point where they leave loopholes, and unscrupulous providers can make interpretations that weren't intended. That's where much of the fraud in the system comes from.

Mr. TOWNS. Mr. Foreman, do you agree?

Mr. FOREMAN. Yes, I do.

Mr. TOWNS. Let me just go back to a question that was raised by my colleague here, Mr. Shays. In section 303 of 3224, it says, "may deprive the providers due process and may also reduce the quality of care to the beneficiary." Without its negative consequences, what do you understand to be the intent of this provision? What do you understand it to be?

Mr. FOREMAN. The overall intent—and I think everyone here would agree with me—is really to shorten the process from the time that it is determined that the price that is being paid by Medicare is either more than the market, excessively more, or grossly excessively more than the marketplace. We don't disagree with that. Where we disagree is the process that is followed in order to determine what is correct or what is the actual market price. And it should not take more than 3 years.

The other thing is that I really don't know—and I might be putting my foot in my mouth—the IG did some investigation as to what the market prices were. I don't know how long it took them to determine what was considered excessive. They may have spent a year; they may have spent 5 years investigating the marketplace. I don't know whether they received all the information that is out there or they just went to one or two vendors and said, "What are you charging?"

Mr. TOWNS. You know, hearings are to collect information and to hope that we can move forward in a very positive kind of way to improve the quality of life for all. With that in mind, what would you consider being reasonable? Can this language be improved so that the goal is achieved and your concerns are satisfied and, at the same time, the issues that are being raised on this side could be satisfied within this? Could you give us some language that you feel might be helpful?

Mr. FOREMAN. As an individual, at this time, I could not. We probably could work something out through our association, yes, to assist in this process.

Let me mention also that if—you say excessive time. If you ask about the change or trying to determine whether the price charged for a walker is excessive or grossly excessive, a year is much, much too long. If you talk about, say, a wheelchair with all the other ancillary products that are attached to it and what should be the proper charge for that, that could be in excess of a year or two. If you talk about oxygen, that could be in excess of a year.

It depends upon the product. So what we're saying is not that we should limit it to a year, because some products could be less than a year. What we're saying is that we do not want to eliminate the procedures that are followed at this time.

Mr. TOWNS. I hear you and I understand you very clearly. That's the reason why I raised this. We're trying to come up with something that works. As you know, right now it's broken, so we're try-

ing to fix it. We're asking for input in that process, and that's what the hearing process is all about.

So, Mr. Doherty, do you have anything you want to add to that?

We're going to move forward, and I want to make certain that we have information to be able to do the kinds of things that we feel are in the best interest of all. There are many times in this place that we do things without really talking with people.

I think that this is an opportunity where the chairman is saying, let us get information; let us talk to everybody. Let us have hearings, and let's see what we can do to correct the problem. We've gone all over this country having hearings on this issue. We want to get information. That's the reason why this process is open.

So, Mr. Doherty, do you have anything you want to add? Now is the time to talk.

Mr. DOHERTY. Yes, I do. We, as an industry, are under a national fee schedule that was just a few years implemented. When the fee schedule was implemented, all the market factors were considered. So, again, as an industry, we're quite confident that the vast majority of the goods that we provide are at a fair market rate. So we're not terribly afraid of the IR process, if it's done fairly.

What we are concerned with is that, if you try to speed the process up and you give HCFA too much authority to be arbitrary, the process will not be fair. I can use the comparison that HCFA made with the Veterans Administration and the Medicare rates as a prime example of how the facts can be distorted or omitted. And that can be very devastating both to provider community and the beneficiary community that depends on our services. These are frail, elderly people that could possibly be denied service or be provided with a deficient service.

So we share your frustration with the time lag in the process but hope that we can solve the problem. We're happy to work with you in solving the problem without throwing the baby out with the bathwater.

Mr. TOWNS. I'm encouraged by that comment, because at least you realize that there are some serious problems and that they should be addressed and that we hope to be able to do that in a very timely fashion.

Let me just move to another issue, Mr. Doherty. You have suggested other features of collecting data. You talked about it. Would this be a separate data base, or can these features be integrated in the data base proposed by H.R. 1850 and, of course, H.R. 3224? Or would we have to create a new system?

Mr. DOHERTY. I don't know that you need to create a new system, but you have to enhance some system within HCFA. HCFA now does not have the capability of monitoring other third-party payers around the country. As a consequence, when they have to make a determination on "inherently reasonable," they just don't have enough data to make a reasonably good decision.

So, yes, HCFA would need to be funded to the degree that they could create a system within HCFA to accumulate this data and make better quality decisions.

Mr. TOWNS. Mr. Foreman, could I hear you on that same issue?

Mr. FOREMAN. I agree with Mr. Doherty. We work in concert with him. But I will say this, that one thing that we cannot do—we recognize this—there cannot be an adversarial relationship.

Mr. TOWNS. Do you want to pull the mic just a little closer to you, please? Pull the microphone just a little closer to you.

Mr. FOREMAN. What we recognize, as an industry, is there cannot be an adversarial relationship between the industry and HCFA and the government. And no one likes, especially myself, as I get a little grayer and I lose some of the hair on top of my head—I want to be known as an ethical provider. I want to walk down the street with my head high. It hurts me to be considered within an industry that practices fraud and abuse, and also keeping prices artificially high.

I think we, as an industry, probably are more aware of the fraud and abuse that is out there and also what items are possibly overpriced and inherently unreasonable. If there was some way that we could work together, using HIDA and NAMES as a conduit with HCFA and the industry, I think that this process could be expedited.

Mr. TOWNS. I agree with you. I think that we definitely need to make some changes here. But let me just raise one other question here before I go, based on the fact that you mentioned that you want to make certain that when you walk down the street that people know that you are a respected businessman. I think that's something that we really want to make certain happens for people who are actually involved in this business.

You could be very helpful, in terms of responding to this particular question, because we're trying to see what we can do to make certain that we cover as much territory as possible in this legislation, but, at the same time, we need to make certain that we cut down on the time.

In an earlier hearing, we learned that although Federal laws are in place to exclude convicted providers from program participation, no one with authority and adequate resources monitors those charged or convicted. Should changes be made to current criminal and civil statutes to improve their effectiveness in sanctioning and deterring health care fraud?

Mr. DOHERTY. We, as an industry, support stiffer penalties and fines, imprisonment, whatever, for fraudulent providers. Part of the problem is that it's too easy to get into the system for the fraudulent providers. Most of the fraudulent providers tend to be single-product dealers.

They jump in—and some of the items that the Inspector General brought today to show—they will jump in and they will do one item, like wound care supplies to nursing home patients, and they just flood the market and exploit the system for a period of time, and then they move on and they pop up somewhere else with another provider number.

These people are really fringe operators and are not representative of the industry. The difficulty is getting rid of those players without using a broad brush and punishing the entire system and the legitimate providers, in particular.

Mr. TOWNS. Do you have any specific recommendations for us?

Mr. DOHERTY. I think that there should be more scrutiny on the front end, in terms of who's allowed to participate in the system. We, as an association, advocate strict standards for participation and entry. All of the legitimate providers now adhere to strict standards. We go through an independent accreditation processes. That would go a long way in terms of weeding out the fringe people that just jump in and jump out with a particular product.

Mr. TOWNS. Mr. Foreman.

Mr. FOREMAN. I must say that HIDA, for many, many years, has always encouraged weeding out the individuals who commit fraud and abuse. What was just said, the last thing that Mr. Doherty said, was the fact that legitimate organizations strive for accreditation, usually through JCAHO, which is the same organization that accredits hospitals.

Most of the fraud and abuse that has occurred has been, as has been said, by the one-product individual or the individuals that are no more than, I guess, scavengers that come in and say, "Oh, here's a problem, or here's something." For example, wound dressings. At a time that the kits were reimbursed for \$17, if you ripped them apart and sold them individually, you could get \$200 for it.

You would not find legitimate dealers doing that. No way that you would want to do something like that, because we're in it for the long run. We run the risk of losing our accreditation and losing our provider number. I think that if Medicare somehow worked with the associations and somehow accredited these individuals or used accreditation by other organizations, an outside, independent organization, it could go a long way toward that.

Mr. TOWNS. Aside from what you've already discussed, such as rulemaking, et cetera, your concerns, what other modifications would you make in this legislation? Do you have any other recommendations for us?

Mr. FOREMAN. At this point, I personally do not. I can't comment.

Mr. TOWNS. Mr. Doherty.

Mr. DOHERTY. No, I think I've made all the recommendations. Again, our primary concern is the due process. Again, our suggestion was to have the funding necessary to let HCFA gather data, so that when they tried to do the IR process, they weren't starting from scratch. That process of gathering the data is the time-consuming part of it, and that's probably the first year or two in a 3-year process. That would be eliminated if that data were continuously provided to HCFA.

Mr. TOWNS. Thank you very much. I really appreciate your testimony. I will say to you that we have some serious problems, and we plan to work to try to correct them. There's a lot of money being wasted, and it's not going to where it's supposed to go. We're talking about quality care and, at the same time, when we learn the fact that we have \$25 billion and \$40 billion—I've heard it as high as \$80 billion. I mean, I've heard all kinds of numbers.

We don't really know how much, but the point is that I think we need to move aggressively to try and correct it. I also agree with you that you have some folks out there that come into the business to defraud it, and you want to sort of get rid of them. They give everybody else a bad name. I understand that. But, at the same time, we need to make certain that we tighten up so they won't be

able to get in, and then we won't have to worry about kicking them out, because they won't be in.

Thank you very much, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

Mr. Davis.

Mr. DAVIS. Thank you.

Let me just say that, as you know, dollars are tight with Medicare. When I go out to town meetings in my senior citizen homes and the like, the first thing they say is, "Let's look at the fraud, the waste, the abuse, overcharges. Get rid of that before you start cutting the increases in our benefits." And we can see from some of the charts here that, whether they are fringe players or whatever, the system doesn't always work as well. I have also seen, in fairness, times when HCFA's reimbursement rates are way too low for some areas. It goes both ways.

I guess my first question is, what do you do to educate HCFA on market prices? Specifically, what actions do your organizations take to ensure that HCFA has the appropriate information on market prices when HCFA announces an item will be reviewed under the inherent reasonableness authority? What do you do at that point? Do you sit back and wait, or do you rush forward?

Mr. DOHERTY. We get involved in the process as early as we can, but that's pretty much in the control of HCFA. So if HCFA is looking at a particular item and the pricing, we, right up front, offer that we want to be involved.

Mr. DAVIS. Well, if I were you, I would be all over HCFA at that point, trying to give them as much data as I could. I wouldn't sit back and wait.

Mr. DOHERTY. Well, we are, but it's not always possible to interact until they are willing to let you interact. In fairness to them, they do have internal processes that they have to go through. So we're always forthcoming, and we're always available and more than interested in participating in a process that affects our future.

Mr. FOREMAN. HIDA has over 800 members that are surveyed whenever a process like this, an IR process, is initiated. What we try to do is, we really try to facilitate the data-gathering for HCFA as much as possible. The reason for it, the more helpful we can be for HCFA, the more they will look to us to try to get as much information as possible. And this is what we provide to them.

Mr. DAVIS. I'm not clear, from your testimony, how the issuance of an interim final regulation interferes with providing information to HCFA. Does the issuance of an interim final regulation interfere with your industry's ability to provide information on market prices to HCFA?

Mr. DOHERTY. Our concern is where the interim falls and who determines the interim. Again, to come up with a reasonable interim solution, one has to have some kind of valid data in order to make that. At present, the system doesn't appear to provide that ability.

Mr. DAVIS. The reality is that Medicare serves 37 million people and spends \$168 billion annually. They are one of the largest purchasers in the health care industry. And it really has the power, in many cases, if not to dictate prices, to radically affect prices. We're seeing this just in terms of doctors' fees, where it's driving

the HMOs, not the other way around, in those cases. Wouldn't you agree with that?

Mr. DOHERTY. Yes, I would. Again, our pricing is under a national fee schedule where we went through a very tight process in terms of scrutiny. I think, if all of our items were put through the IR process in a fair way, we would find that the vast majority of them are at fair market pricing.

Mr. DAVIS. What we're finding, at least my observation is, for example, in the medical profession, the fees are much—have really driven down the fees that doctors are able to charge now, not just for Medicare, but driving them down because the managed care organizations are adopting those schedules.

Mr. DOHERTY. We brought a couple of charts that indicate what our industry has experienced over the last 10 years. We just picked two items: electric hospital beds and oxygen. Over the last 10 years, in real dollar terms, our pricing has remained flat or gone down. And in more realistic terms, including a small inflationary factor of 3 percent, oxygen was decreased over the last 10 years by 50 percent, and beds were in the range of 40 percent. So we certainly haven't been seeing any increases in prices and, in reality, have seen large decreases for a decade.

Mr. DAVIS. Industry testimony, I think, has refuted two of HCFA's justifications for a price adjustment of home oxygen rates, but HCFA reports, despite this, it is proceeding with the adjustment of price. Now, what suggested adjustments has your organization made for the home oxygen rates? If HCFA's change in technology and higher prevailing charges arguments were both determined to be not valid, why is HCFA proceeding with the price adjustment for home oxygen services?

Mr. DOHERTY. That's a good question. We've engaged to have studies done comparing the Veterans Administration pricing with Medicare pricing. And the conclusion that we come to is that Medicare is either equal to, or less than, what the VA is paying when you take a fair look at it and include all the services and make it a comparison of apples and apples.

Mr. DAVIS. I would yield back, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

My co-chair and actually chairman of the Management Subcommittee.

Mr. HORN. Thank you, Mr. Chairman.

I am delighted to hear of your concern about some of the contractors that aren't quite above-board. I think that's commendable, because, heaven knows, on a vast undertaking such as this, we need the help of industry that wants to get rid of the people that are giving any industry a bad name.

This is not a new phenomenon in America. In the Civil War, we had contractors in the North selling bad pork to the Union Army. A joint committee of the Senate and the House was created to go after that kind of fraud and abuse and scandals that they were. And they did a pretty good job. In the Second World War, a Senator by the name of Harry Truman happened to head the investigating committee on similar corrupt contractors.

Well, we don't have a Civil War; we don't have a Second World War, thank heavens, but the biggest game in town, equal to a war,

is really the Health Care Financing Agency, which administers Medicare and Medicaid. We need, Mr. Chairman, to get, jointly, their top people up here to go over how that internal process works, with such words that Congress has guided them—I think misguided them—on “grossly excessive.” I think that’s a crazy standard.

I think what we ought to talk about is competition, market prices, and flexibility for the Health Care Financing Administration. Personally, where I’m leaning on this—I agree with everything Mr. Davis said; he’s got the right caveats on that—but we ought to have an agency that is created, almost like a Government corporation, to have flexibility and to administer that agency just as every major health care practitioner administers itself, be it the major hospital of 500 to 1,000, or be it a major health maintenance organization with branches all over the place.

As you know, we have now a number of nationwide providers. They do not go through this, what the Health Care Financing Administration has to go through. They have to look at competition, market share, and get respect from the providers of services to their tremendous volume. And believe me, people want to deal with them. Why? Because they have a steady stream of customers.

I think Medicare, obviously, Medicaid has a steady stream of customers, but the Government is not getting any of the benefits that the private sector automatically gets when they enter the market. We need to so structure the Health Care Financing Agency so that the Government, and thus the taxpayers, you and me who pay taxes, get the benefits of that volume and get the benefits of effectiveness and efficiency, which we are not getting now.

So while we go after legitimate fraud and abuse, we need to also go after lackadaisical, lethargic management. And the Congress, in its previous acts, as we both read them, has substantial lackadaisical management built in. What we need are changing those rules, getting administrators in these agencies that look at as the vast empire it is, and do the right thing by the customer, namely the people 65 and over, and in Medicaid, the economically poor, financially, and make sure they get the services, but they get the services at a reasonable, and we get the bills at a reasonable price.

I do not think that’s too much to ask for of a Government agency, and it is the Congress’ job to make sure that it happens. So I think we ought to hold the hearings that need to be held to make sure that it happens.

Mr. SHAYS. I thank the gentleman and I agree with him.

Before we adjourn, I would like the Inspector General to come up. I would like you all to stay here. I want to have a definition of where the dispute is and not necessarily a resolution of the dispute. So I’m going to ask both of you to stay.

Mr. Foreman, if you would move your mic over to Mr. Mangano.

Mr. FOREMAN. Oh, sure.

Mr. SHAYS. I want to make reference to the oxygen concentrator. I want to have your perception, Mr. Inspector General, Mr. Mangano, of what you think the dispute is about. I would like you all to respond. I’m not looking to know who is right and wrong.

Mr. MANGANO. OK. It’s been a couple of years since I’ve been involved with this, but let me tell you what I do remember of it. In

the report that we released in 1991, in which we were trying to compare prices for oxygen concentrators at the Veterans Administration versus Medicare, we found that Medicare was paying about 170 percent more than the Veterans Administration was.

We made our recommendations to HCFA and in several congressional hearings. In response to that, HCFA then decided, "OK, we have your information; we're going to go out and do our own market surveys to find out what the difference is." When they completed their market surveys, they came to the conclusion that, in their interim regulation, that they would recommend about a 40 percent reduction in oxygen concentrator prices.

Mr. SHAYS. Following the due process.

Mr. MANGANO. That's correct, the inherent reasonableness process. The next step, the Congress took up the issue itself, and in the reconciliation bill last year had proposed a phased-in reduction of about 30 percent.

Now, one other point that I would make.

Mr. SHAYS. Is that because they felt the process was taking too long?

Mr. MANGANO. I don't know. I do know that there were a number of Members of Congress who were very interested in the issue, that had talked with HCFA and the industry.

Mr. SHAYS. But I'm struck by the fact that there's another time that Congress did step in.

Mr. MANGANO. That's correct.

Mr. SHAYS. And that was a gigantic savings. But that was on one issue?

Mr. MANGANO. That's correct.

Mr. SHAYS. But what was the other issue? There was one where it went from \$190 to \$14 million, in your testimony.

Mr. MANGANO. Well, there was certainly the seat-lift chairs.

Mr. SHAYS. Yes, the seat-lift chairs.

Mr. MANGANO. The intraocular lenses were like that; a number of them.

Mr. SHAYS. But ideally the system shouldn't be Government—we shouldn't have to pass a law on this.

Mr. MANGANO. Absolutely.

Mr. SHAYS. Now, what is your understanding of what the criticism, though, is of the way the Inspector General and GAO report.

Mr. MANGANO. OK. The other point that I want to make is that there was an issue that was brought up fairly early on, after we completed our report, in terms of the service level, that Medicare receives far more services than the Veterans Administration people do for that.

We then went out and did another review, completed in 1994, in which we took a look at the service level for Medicare beneficiaries. We found that about half of the beneficiaries receive no patient services, and about 10 percent receive no equipment services. This was in a random survey of Medicare beneficiaries.

That was not surprising to us, because, as we took a look at HCFA's regulations, the regulations do fail to specify the precise services that should be delivered.

Mr. SHAYS. So, in fact, if HCFA was paying more, then there should be a definition that there is more service involved.

Mr. MANGANO. That's correct.

Mr. SHAYS. Now, I would gather the response from the industry would be—and I would be happy to have you respond—that you would say that with the hospital, you provide it to the hospital, and it's not patient-to-patient, whereas in Medicare, it's patient-to-patient.

Mr. FOREMAN. That's right.

Mr. SHAYS. Would you use the mic? I'm sorry. If you two would share that mic a second.

Mr. FOREMAN. I agree with you that it is patient-to-patient versus in a hospital where you have the entire patient mix.

Mr. SHAYS. But that would be your argument.

Mr. FOREMAN. No, that's not the only argument.

Mr. SHAYS. OK.

Mr. FOREMAN. I have to address the issue concerning oxygen concentrators in 1991, because I did get an RFP, a request for proposal, from the VA. And the VA request was that they wanted to know what it would cost them or we would charge them for 120 oxygen concentrators. There was no specification as to what type of service, what condition the oxygen concentrator should be, and also as to what was the actual oxygen content that was generated by the concentrator itself.

We declined to bid on the concentrator proposal. We saw the bid, or we were aware of the amount that was paid after the contract was let. We could only determine that the amount that was paid for those concentrators was less than \$50 apiece. What was done was that these concentrators were dumped on the individuals. There was no provision concerning any type of backup or portability provided to these patients. There was nothing concerning any disposable supplies such as tubing, cannulas, water traps, or such.

Mr. SHAYS. And your point to us is that Medicare would make that requirement?

Mr. FOREMAN. Medicare would make that requirement that we have to provide it.

Mr. SHAYS. But that would be the rule or the exception with the VA, as far as you are concerned?

Mr. FOREMAN. It would be the exception if they asked for that. What they ask for really is an unbundled service. They are going a la carte and saying, provide the oxygen concentrators. Then, if you provide any other service that is requested by us, we will pay you for it.

Mr. SHAYS. Mr. Doherty.

Mr. DOHERTY. Mr. Chairman, Medicare, for example, does not pay to rent oxygen concentrators. Medicare has a modality-neutral system of paying for oxygen therapy, and they pay a flat rate regardless of the equipment that is used. The VA system chooses to rent oxygen concentrators, and, as Mr. Foreman said, they provide all of the other equipment and services that go along with it a la carte.

So when you look at the total amount of dollars paid for a typical VA patient, it's either equal to or greater than what Medicare pays for the same group of services, but the quality of service provided to the Medicare patient, in my estimation, is very much higher. As

a provider that sees what's going on and as a veteran, if I ever had lung disease, I certainly wouldn't want to be treated under any of the VA contracts. Medicare gets a good buy.

Mr. SHAYS. Well, don't get carried away here. No, no, I mean, with all due respect here.

I get the general sense of where you're coming from. You are saying, you have to compare the like service. Your basic argument is that Medicare doesn't buy in bulk, which is kind of something that I'm kind of surprised about, but that it's individual-to-individual.

Is there an ability for you to go back and look at this in a little more depth? I'm not talking about a long study, but give me, in writing, some of the responses to this issue?

Mr. MANGANO. I think we certainly could. But what I might want to suggest is that we get the information that HCFA developed in their market survey.

Mr. SHAYS. OK.

Mr. MANGANO. Maybe that would provide the information.

Mr. SHAYS. And the point is that they went through that process.

Let me just tell you where I find common ground and where I don't find common ground. First off, I have learned a lot of new things. One is, I have learned that a test of "grossly excessive" or even "excessive" is not acceptable to me.

I've learned that, in my judgment, the process shouldn't even take a year, considering that the market is so competitive today. I would like there almost to be an instant ability for Medicare to get that same value and price. How we do that is interesting to me.

I don't know if I would throw out the due process concept, but I do have some sympathy for the industry. I do know that when we empower a bureaucracy, the bureaucracy can just say, "Screw you. This is it. I'm sorry your business is going under." And I do think that, for a large purchaser, there has to be some kind of ability to provide a response to those who actually deal with a large bureaucracy. But that process clearly has to be speeded up.

You will see something like what I propose, I believe, unless you come in with better suggestions. So I'm open to that. And I would just say to you that this has been a very interesting hearing, but it is not a hearing that ends today. If you don't know me, you should know Mr. Horn. He will not give up on it.

Mr. Horn.

Mr. HORN. May I ask a question? It might have been covered when I was out of the room for another hearing. But I've studied the health care matter, I guess, since 1952, and one of the things I've noticed in recent years is, the greatest increase in cost of any component in the health care system is the medical health care equipment component. That seems to rise above everything else.

Now, that's unusual for anybody that knows the history of technology, be it in Europe or the United States. As technology advance—and, of course, computers are the wonderful example of this, and I don't say it applies to everything—but, as technology advances, you have the advantage of volume, where it becomes more accessible to more people, and you have improvements that give you a greater capacity.

One of our colleagues has said about computer productivity and capacity that, if the Federal Government had that capacity and

productivity, in relation to the private sector, that we would only have four people running the Federal Government. That's how vast the computer increase and availability has been.

So it lowers the cost per unit. But I don't see medical health care equipment costs being lowered by the cost per unit, either based on technological improvement or based on volume of sales. I just wondered, what is your thinking in this area? What explains why your segment of the health care industry has the greatest cost increases of any segment of the health care industry, and way ahead, four times inflation, may I see, four times CPI?

Go ahead.

Mr. SHAYS. I'm sorry. The Inspector General, you are free. Thank you very much. We appreciate that.

We're going to close up in a second. I just didn't want to keep him any longer.

Mr. FOREMAN. What has occurred in the last 10 or 15 years is the result of DRGs, diagnostic-related groups. What has happened is that hospitals have found it economically efficient to get the patient out of the hospital as quickly as possible. The technology has improved to the point that people are living longer. As a consequence, they are living longer at home, so the amount of products that are available to help the caregiver in the home to provide the service to the patient is expanding.

The quality of life is improving for an awful lot of patients that are staying at home. If you look at the vast array of wheelchairs and ambulatory aids, it has increased significantly. If we just talk of what we had before, yes, patients didn't die at home 10 or 15 years ago. God forbid that you should have a relative that you didn't give him or her the last possible bit of care available, which meant you put him in the hospital; he stayed on the ventilator as long as possible.

We now have patients going home—at least we do—that are on ventilators, that have been there a number of years. We can't pull the plug on these patients, but we do know that it is much more feasible, from the standpoint of dollars and cents, to treat that patient at home than to keep him in an intensive ward within the hospital itself.

Mr. HORN. Well, I completely agree with you, but has progress been made, technologically, in that ventilator, and has the volume increased that would mean you have a more efficient product line coming out of the factory and that the unit cost would go down? Has the unit cost gone down? You're taking the ventilator. I don't have the slightest idea.

Mr. FOREMAN. I believe it has.

Mr. HORN. Because I know it's four times CPI, usually.

Mr. FOREMAN. If we take a look at the charts over on the side here, if we just applied the CPI to what the charge was approximately 10 or 12 years ago, the cost for providing oxygen services, therapy, to a home-bound patient would have been double what it is right now. What is it? Need is the mother of invention.

Mr. HORN. Necessity, yes.

Mr. FOREMAN. Somewhere along the line, something is going to happen. I know the industry, I know manufacturers are looking at ways of bringing down the cost as much as possible. Yes, we would

like to bring down the cost as much as possible. I feel that way. After all, in the next few years, I happen to be one of the individuals that are going to be on Medicare, and I think it's getting awful close. I think the last one is—it coincides with my retirement date that we're going to run out of money. I don't want that to happen.

Mr. HORN. That's what concerns me. We have trustees that only reluctantly have revealed that we have a deficit. And we said, "Why wait 5 years? Let's start dealing with that right now." In essence, in part, this hearing helps, in a small way, to deal with that major deficit that is coming in Medicare money.

Mr. FOREMAN. Well, one of the things I was going to suggest is that the chairman ask the IG representative to go back and look at this figure again and try to analyze it. I think the time to really get together with industry and the associations of industry is not after they have come to the conclusion. I think the time is while they are actually doing the study and say, "OK. Here's the data that we're using. What are the data that you are using?" Get the two together in order to come up with a reasonable price as to what should be the reimbursement amount.

Mr. HORN. Well, that's certainly a reasonable suggestion. I would hope the Inspector General and the Health Care Financing Administration would have a cooperative partnership with industry, because we need to do things and make decisions in a much more rapid order than we are. Time is money, and time, in this case, means the cost rapidly increases because nobody has dealt with the basic decisions.

Mr. SHAYS. I thank the gentleman.

We sure are going to change "grossly excessive" to maybe "reasonable or fair," but we will find a term. Let me just say that HCFA was invited to testify today, but Dr. Vladeck decided that 10 days, which was the amount of time we gave him, was not enough time to get the testimony cleared through HCFA and OMB. I guess we should have given him more time, but I do want the record to show that evidently HCFA had a hard time with 10 days.

Mr. HORN. Well, we can send them all of this testimony and then say, "We'd like to sit down and chat."

Mr. SHAYS. We will do that.

I would like to thank the full committee staff person, Marty Morgan, who has been involved in these issues; and my own staff, Kate Hickey; and the minority staff, Cheryl Phelps; as well as our transcriber, Jan delMonte, for their work on this hearing.

Mr. HORN. May I add that we also thank our own staff on Government Management, Information, and Technology, J. Russell George, the staff director and counsel; Mark Uncapher, the professional staff member and counsel for this hearing; Andrew Richardson, the subcommittee clerk.

Mr. SHAYS. I didn't thank my clerk. Sorry, Tom.

Let me just say, the hearing is closed, and I thank everyone for participating.

[Whereupon, at 12:40 p.m., the subcommittees were adjourned.]

[The prepared statements of Hon. Constance A. Morella, Hon. Carolyn B. Maloney, and Hon. Gene Green, and additional information submitted for the hearing record follow:]

Statement of the Honorable Constance A. Morella
Before the Government Reform and Oversight
Subcommittee on Human Resources and Intergovernmental Relations
Health Care Fraud
May 2, 1996

Mr. Chairman, I want to thank you for holding this hearing to discuss legislation to reduce health care fraud, waste and abuse. Although the Congress has had lengthy debates over how to cut Medicare and Medicaid spending, we have not spent enough time attacking the biggest problems plaguing Medicare -- waste, fraud, and abuse. Before we raise copayments, increase premiums, or raise costs for providers, we must implement plans to reduce waste, fraud and abuse. Our Medicare system is vulnerable to billions of dollars in unnecessary payments. According to a GAO report, Medicare pays higher than market rates for certain services and supplies, and Medicare does not question payment of claims for improbably high charges or manipulated billing codes. GAO also found that Medicare's checks on the legitimacy of providers are too superficial to detect a scam.

Several of my constituents have shared their experiences with waste in the Medicare system. I have with me a Medicare payment check for 1 cent that was mailed to a constituent of mine in Rockville, Maryland. What an incredible waste! We all have countless examples of waste that we could share, but we must focus on ways to eliminate such waste. I look forward to today's hearing because we will focus on solutions. I hope it will shed light on action the Congress should take to effectively eliminate waste, fraud and abuse.

I look forward to hearing from our witnesses who will discuss three pieces of legislation that we should consider: Representative Schiff's

bill, H.R. 3224; Representative Towns' bill, H.R. 1850; and Representative Quinn's bill, H.R. 2480. I welcome my Colleague, Jack Quinn, who has been a leader on this issue.

Mr. Chairman, I strongly support Medicare reform. We must take responsibility for our entitlement spending before it spirals out of control. But before we cut Medicare and Medicaid spending, we must ensure that we are spending our health care dollars wisely. Legislation that will substantially reduce fraud, waste and abuse is long overdue, and I thank the Chairman, the bills' sponsors, and our panel for bringing this issue to the forefront.

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OPENING STATEMENT -- HON. CAROLYN B. MALONEY
HEARING ON H.R. 3224, THE HEALTH CARE FRAUD AND ABUSE PREVENTION
ACT OF 1996, H.R. 1850, THE HEALTH CARE FRAUD AND ABUSE ACT OF 1995
AND H.R. 2480, INSPECTOR GENERAL FOR MEDICARE AND MEDICAID

May 2, 1996

Thank you Mr. Chairman.

I would like first to commend Chairman Shays and Ranking Member Towns for their diligence and hard work in examining the issue of fraud and abuse in the Medicare and Medicaid programs. The oversight hearings you have conducted, and the legislation we are considering today, are evidence of the serious attention you have given to a very difficult and expensive problem facing federally administered health care programs.

The breadth of that problem is staggering. Federal spending on Medicare and Medicaid in FY 1995 was \$264 billion. It is estimated that of that amount, up to 10%, or \$25 billion is lost to fraudulent and abusive practices. This is clearly a situation Congress must address at a time when federal resources are becoming ever more scarce.

H.R. 1850 and H.R. 3224 both strengthen the Inspector Generals of various departments by requiring audits, criminal investigations and evaluations of health care fraud and abuse. They also require more coordination between the Inspectors General and the State agencies and include enhanced data-sharing requirements. These are good ideas in our fight eliminate health care fraud and save taxpayer dollars.

H.R. 2480, introduced by Rep. Quinn last October, would establish an independent agency known as the Office of the Inspector for Medicare and Medicaid to coordinate audits, investigation, inspections, and other activities for curbing fraud and abuse in those programs. While I commend my colleague from New York for his efforts in this area, I am not sure that this is the proper way to proceed. It seems to me that it would be better to devote more resources to the current Inspector General's office at the Department of Health and Human Services than to create a new independent agency, with all of the overhead cost and bureaucratic duplication that would entail.

I look forward to hearing from our witnesses today in our continuing efforts to eliminate fraud and abuse in federal health care programs. Thank you Mr. Chairman

Statement of Representative Gene Green
Subcommittee on Human Resources and Intergovernmental Relations
May 2, 1996

Thank you, Mr. Chairman for calling this hearing on health care fraud and abuse. I have said before that this is one issue that both parties in Congress and the Clinton Administration agree needs to be addressed and I commend Chairman Shays, Mr. Schiff, and my ranking member Mr. Towns for their work in this area.

During earlier hearings on this issue, I was surprised how difficult it is for the government to change prices on Medicare reimbursements and sever links with fraudulent providers, let alone totally exclude them from the system. It is my hope that our committee can have a positive influence on these problems and create real solutions.

In today's hearing I would like to explore why some problems raised in past hearings did not make it into the new legislation, even though the bill has been strengthened. For example, the Justice Department found that the prohibition of the attorney for the government from reducing the imprisonment time for a defendant in exchange for payment of a fine has inhibited the government's ability to negotiate a settlement.

I look forward to today's hearing and advancing the work of this subcommittee on combating health care fraud and abuse.



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Marcia J. Radosevich, Ph.D.
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Mr. Chairman, Members of the Subcommittees, thank you for the opportunity to submit a statement on the crucial waste, fraud, and abuse provisions of H.R. 3224. I commend your leadership in the examination of this problem and your attention to the possibilities for improvement within the Medicare system.

Since 1987, HPR has been developing and perfecting software programs which expose and correct waste, fraud, and abuse in the Medicare program. Our clients include more than 240 of the nation's largest managed care organizations, insurance carriers, Blue/Cross/Blue Shield plans, as well as a growing number of provider-based delivery systems.

Before founding HPR Inc., I was the Regional Director of Managed Health Care Services, Inc. (MCHS) where I managed a preferred provider network for the Travelers Insurance Companies. Prior to MCHS, I managed the Chrysler, General Motors and United Auto Workers accounts for the Health Data Institute in Lexington, Massachusetts. For over twenty years, I have worked to address unnecessary losses of revenue in private sector health care. At HPR we address abuses within the system through cost containment software products, focusing on losses directly attributable to incorrect or inappropriate medical claims. I wish to underscore the wisdom and importance of Congressional initiatives, such as this hearing, to simply begin use of available technology to save money now.

As you know, health care physicians receive a specific Medicare payment for every covered medical service provided to beneficiaries; each service is assigned a code within the American Medical Association's Physician's Current Procedural Terminology (CPT-4) manual. Medicare and most private insurers pay physicians using fee schedules which follow CPT code guidelines. HPR's technology enables physicians, health care experts, and computer professionals to ensure claims for payment are consistent with Medicare Policy (*Medicare CodeReview*), as well as prevent inappropriate code combinations or code manipulation (*CodeReview*). *Medicare CodeReview* and *CodeReview* detect, correct, and document errors in physician claims. These programs provide consistent and objective claims review by applying the CPT coding criteria for medicine, surgery, laboratory, pathology, radiology, and anesthesiology.

Medicare CodeReview utilizes a comprehensive, Medicare-specific knowledge base that enables a user to process claims according to Medicare's coding guidelines. Medicare PartB carriers, or other payers using a fee schedule similar to Medicare's fee schedule, are the typical users of this application. The guidelines in this program are consistent nationally and are regularly updated to ensure compliance with HCFA guidelines and accuracy. *Medicare CodeReview* includes the following Medicare-specific detection capabilities:

- Rebundling guidelines
- Bundled/Excluded Services
- Carrier-Priced Services
- Invalid Codes
- Noncovered Services
- Restricted Coverage Services
- Injection Services
- Relative Value Units for Surgical Procedures

- Pre and Post Operative Global Fee Periods
- "Incidental to" Services
- Physical Therapy Services
- Billable Medical Supplies
- Modifier Logic

CodeReview, a patented software product (No. 5,253,264), identifies and corrects inappropriate CPT codes on claims submitted by physicians. Among its capacities are:

- Unbundling
- Fragmentation
- Upcoding
- Miscoding
- Place of Service Logic
- Superseded Codes
- Duplicate Procedure Logic
- Cross-Section Logic
- Add-on Procedure Logic
- Age and Gender Edits
- Historical Claims Processing
- Invalid Codes
- Assistant surgeon criteria
- Global Service Periods
- Mutually Exclusive Procedures

Attached are examples of how errors can be detected using *Medicare CodeReview* and *CodeReview*.

As an expert, investigative source for the GAO's May, 1995 study entitled "Commercial Technology Could Save Billions Lost to Billing Abuse," HPR analyzed over 200,000 paid Medicare claims using our *Medicare CodeReview* and *CodeReview* software. In its study, the GAO concluded that the use of commercial code-editing software by Medicare contractors could have reduced federal outlays for physician services and supplies by more than \$640 million in 1994 alone.

HCFA has certainly begun a viable, crucial process of cost containment in the public sector. Implementation of a Medicare Transaction System at HCFA does offer potential improvements in Medicare claims processing. However, private sector initiatives have already proven successful at creating significant savings by eliminating needless claims violations within Medicare. As demonstrated by the 1995 GAO study, the possibilities for this kind of savings in the public sector exist now and are readily available. The public-sector claims payment industry can answer the public need for "automated data processing equipment...as effective (or more effective) in detecting code manipulations, unbundling, global service violations, double billings, and other forms of waste, fraud, and abuse as equipment...used in processing claims for private insurance..." (Title III, Sec.307, H.R. 3224) HPR fully supports Congressional efforts to realize potential savings through commercial code software and I welcome any opportunity to be of further assistance.

Claim #1: CodeReview Example

In this claim, code 20102 (exploration of an abdominal wound) is a new code in the 1996 CPT Manual. According to the CPT guidelines for this code, the exploration of the abdomen should not be reported when a definitive abdominal procedure is performed. In this case, the definitive procedure is the resection of small intestine (44120). Therefore, code 20102 is denied as part of 44120.

In addition, code 49000 is denied as part of the global services for 44120. HPR's physicians and surgical consultants indicate the exploration of the abdomen is virtually always performed with any intra-abdominal procedure, is considered standard medical practice, and has always been considered part of an intra-abdominal operation. Furthermore, code 49000 is listed in the AMA CPT Manual as a "separate procedure", meaning it does not warrant additional identification, since it is commonly carried out as an integral part of any intra-abdominal procedure.

Claim #2: Medicare CodeReview Example

In this claim, Medicare CodeReview performs multiple functions, according to HCFA's policies. First, Medicare CodeReview denies code A4550(surgical tray) as part of the global services for the skin lesion excisions. According to HCFA's guidelines for "Billable Medical Supplies", providers should be paid for A4550 only with certain procedures performed in the physicians' office. Code 11423 is not one of these procedures. Therefore, HCFA considers the surgical tray as part of the global services for the skin lesion excision procedure code. Second, code A4649 (miscellaneous surgical supply) has a status of "B" in the Federal Register. According to HCFA's definition of codes with a B status, payment for the B status services are always bundled into payment for other services to which they are incident. In this case, code A4649 is excluded as part of the global services for the skin lesion excision. Finally, Medicare CodeReview attaches a modifier -51 to codes 11422 and 11421, indicating these codes represent secondary procedures. According to HCFA, the surgical procedures with the lower relative value units (RVUs) should be reimbursed as secondary procedures.

CodeReview(R) 5.2
01/29/96

Pend Report
Claim = 03, Pend = 05

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INPUT CODES		CHARGE	ALLOWED
1. 20102	01/02/96 explore wound, abdomen	600.00	500.00
2. 44120	01/02/96 remove small intestine(part or all)	1500.00	1500.00
3. 49000	01/02/96 explore abdomen as sole procedure	1000.00	500.00

RECOMMENDED CODE		ADJUSTED CHARGE
1A 44120	01/02/96 remove small intestine(part or all)	3100.00

EXPLANATIONS

1. 20102 01/02/96 explore wound, abdomen
EXCLUDED: This code is part of the more global code 44120.
2. 44120 01/02/96 remove small intestine(part or all)
ACCEPTED: This code has been accepted with no change.
3. 49000 01/02/96 explore abdomen (as sole procedure)
EXCLUDED: This procedure is incidental to the accepted code(s).

CodeReview(R)
PC COBOL TESTING COMPANY
HISTORICAL AUDITING RECOMMENDATION REPORT - ALL CLAIMS
ALL CLAIM TYPES
PERIOD: 01/01/1993 - 02/08/1994

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02/08/94 10:28

PROGRAM: HPRBRPT

ARTIFICIAL CLAIM ID: 0000000089

KB ID: 99

CURRENT CLAIM NUMBER: 0006

PATIENT ID: PATIENT ID

PATIENT DOB: 01/01/1959

PATIENT SEX: F

PROVIDER ID:

ENTERED DATE: 02/08/1994

** INPUT CODES ***

R	DOS	POS	CODE	MOD	DESCRIPTION/HISTORICAL CLAIM NUMBER	CHG/ALLOW
	08/21/93	11	11423-LT		excise skin lesion,scp/nk/hd/ft/gen	275.00
						250.00
	08/21/93	11	11422-LT		excise skin lesion,scp/nk/hd/ft/gen	225.00
						175.00
	08/21/93	11	11421-LT		excise skin lesion,scp/nk/hd/ft/gen	165.00
						70.00
M	08/21/93	11	A4550		surgical trays	75.00
						75.00
M	08/21/93	11	A4649		surgical supply; miscellaneous	25.00
						25.00

** OUTPUT CODES ***

R	DOS	RVU	CODE	MOD	DESCRIPTION	CHG/ALLOW
	08/21/93	3.66	11423-LT		excise skin lesion,scp/nk/hd/ft/gen	275.00
						250.00
	08/21/93	2.81	11422-LT,51		excise skin lesion,scp/nk/hd/ft/gen	225.00
						175.00
	08/21/93	2.32	11421-LT,51		excise skin lesion,scp/nk/hd/ft/gen	165.00

** MESSAGES ***

08/21/93 11423-LT excise skin lesion,scp/nk/hd/ft/gen
ACCEPTED: This code has been accepted with no change.

08/21/93 11422-LT excise skin lesion,scp/nk/hd/ft/gen
ACCEPTED: This code has been accepted with no change.

08/21/93 11421-LT excise skin lesion,scp/nk/hd/ft/gen
ACCEPTED: This code has been accepted with no change.

08/21/93 A4550 surgical trays

DENIED: Medicare does not pay for surgical trays used in an office with one of the accompanying procedures.

08/21/93 A4649 surgical supply; miscellaneous

DENIED: Medicare's payment for this service is included in the reimbursement for the primary procedure/service.

NATIONAL ALLIANCE FOR INFUSION THERAPY

The National Alliance for Infusion Therapy ("NAIT"), representing national manufacturers and providers involved in the provision of home infusion therapy, submits these comments for the record of the hearing held by two subcommittees of the House Committee on Government Reform and Oversight on May 2, 1996. The subject of the hearing was H.R. 3224, a bill that addresses health care fraud and abuse issues.

NAIT generally supports your efforts to increase the ability of the federal government to combat fraudulent or abusive practices. We share the Committee's interest in stiffening penalties for those who would defraud the Medicare program. Over the past several years, the infusion therapy industry has had its share of adverse publicity, largely due to the well-publicized acts of a small number of providers. As an industry and as an association devoted to improving patient service and to ensuring that home infusion has a rightful place in the future spectrum of health care delivery, we look to the day when the policy debate is centered on price, quality, and service, and not on how the activities of a small number of willful practitioners color the perception of an entire industry.

Before addressing the specific provisions of H.R. 3224, we would like to describe briefly what home infusion therapy is and how it is provided. Infusion therapy primarily involves the administration of a drug, nutrient solution, or other fluid into the body through a needle or catheter. Typically, infusion therapy means that a drug is administered parenterally, or outside the digestive tract. The usual route is intravenous, but other routes are feasible as well. In the case of enteral nutrition, nutrients are delivered directly into a patient's digestive tract through a feeding tube.

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The drug therapies most commonly administered in the home include antibiotic therapy, chemotherapy, pain management therapy, and parenteral and enteral nutrition. It should be noted, however, that infusion therapy is a fundamental, medically necessary treatment for over 200 diagnoses. The most common include infections, AIDS, cancer, severe pain, and nutritional disorders. Before the development of home infusion therapy, these patients had to be hospitalized, sometimes for weeks and months at a time.

Infusion therapy has been provided in acute inpatient settings for several decades. The first infusion therapies introduced into the home setting during the 1970s were the nutritional therapies - parenteral and enteral nutrition. In the mid-1980s, antibiotic therapy, chemotherapy, pain management and other therapies were added to the spectrum of infusion therapies that commonly are provided to patients in their homes.

Properly provided, home infusion therapy is dramatically cost-effective compared to inpatient hospital care, and enables quite ill patients to receive a level of care in their homes which as recently as 15 years ago was only available in tertiary care institutions. The new home infusion therapy providers that developed in the last decade utilize technological developments and advancements in home nursing and pharmacy practice to create a "hospital without walls" concept of home care. Any infusion requires two basic types of equipment: (1) an access device (usually a catheter) through which the drug or solution enters the body, and (2) an infusion device (usually a pump or gravity drip system) to move the solution from its container into the delivery system and then into the patient.

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It is very important to note that the delivery of the supplies and equipment to patients is not the sum and substance of home infusion therapy. For home infusion therapy to be successful, or even possible in the home setting, specially trained nurses and pharmacists are required to train the patient and/or the caregiver, closely monitor changes in patient condition, respond to emergencies and changes in regimen, and to collaborate with the patient's physician to carry out a patient-specific plan of care. This is especially true for the Medicare patient population, which generally is more vulnerable and frail than the private payer population.

Having described home infusion therapy, we would like to offer our thoughts about a provision in H.R. 3224 which does concern us. Section 303 would empower and direct HCFA to use its so-called "inherent reasonableness" authority more quickly and more effectively. Specifically, it would require HCFA to make an adjustment in payment for an item that is a candidate for the application of inherent reasonableness, through an interim final regulation "issued not later than 1 year after the Secretary initially proposes to make the adjustment". In his testimony at this hearing, Principal Deputy Inspector General Michael F. Mangano identified two infusion therapies, enteral nutrition and parenteral nutrition (hereinafter referred to as "PEN"), as candidates for the application of inherent reasonableness. In light of the long history of how HCFA has attempted to regulate PEN in the past, we hope you will understand why we are very wary of making it any easier for HCFA to put aside the statutorily-established payment methodology for PEN and substitute its own perception of the "market" to determine the payment rate.

NATIONAL ALLIANCE FOR INFUSION THERAPY

I. HISTORY OF MEDICARE COVERAGE FOR PEN

The Medicare program does not cover PEN, or infusion therapy generally, in a logical manner. HCFA regulates infusion therapy by grouping it with the delivery of products with which it has little in common. PEN therapies are covered under the prosthetic device benefit of Medicare Part B, while other infusion therapies are covered at carrier discretion under the durable medical equipment benefit. Neither benefit explicitly recognizes the professional services involved in the provision of these therapies. HCFA interprets both the prosthetic device and durable medical equipment benefits as covering only the drugs or nutrients, supplies and equipment used in the provision of therapy. While it is commonly understood within HCFA that it is the nursing and pharmaceutical services that enable patients to receive care in the home at all, Medicare's coverage criteria still do not acknowledge this critical component.

A natural question arises at this point: What does HCFA gain by defining home infusion therapy simply as the delivery of products? The answer is simple -- short-term cost savings. If HCFA can cling to a product-only definition, then it can advocate for product-only reimbursement. HCFA can then trim the current payment so that not one dollar of reimbursement is applied to the provision of services. At best, this position is simply disingenuous, and at worst, it is bad clinical practice and constitutes a poor basis for the creation of new policies to guide the future.

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This has resulted, year after year, in a tug of war between HCFA and home infusion therapy providers over HCFA's efforts to reduce reimbursement. HCFA's proposed cuts have varied over the years, but they would all accomplish the same thing, which is to halt payment that may possibly reflect the provision of professional services. Each time, we have suggested alternative cuts that we believe make more sense and do not threaten patients, and Congress generally has responded well to our suggestions.

We do not believe that granting HCFA greater authority to undercut payment rates established pursuant to statute would improve HCFA's understanding or policies regarding PEN.

The PEN community can offer a special perspective on inherent reasonableness, because PEN was once the target of an effort within HCFA to utilize its inherent reasonableness authority. In 1984, HCFA attempted to establish national rates for PEN based on its regulatory authority for inherent reasonableness that existed prior to the enactment of the current statute in 1986. HCFA acted quickly, and attempted to produce rates within a three month time period. The analysis conducted by HCFA was of poor quality, and was conducted with questionable methods. No allowance was made for the fact that Medicare only covers enteral formula when it is provided by tube.

The resulting rates were widely criticized by the medical community. At the urging of the House Ways & Means Committee, senior HCFA officials examined the analysis, and

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decided to ignore the findings and begin again. Congress intervened in 1986 by mandating the use of the lowest charge level payment methodology for PEN, which continues to the present time. As described by one Congressional staff person at the time, HCFA's effort to adjust PEN payment rates was "more inherent than reasonable." In other words, Congress stepped in to prevent HCFA from implementing "inherent reasonableness" in an inappropriate way. Unfortunately, HCFA's perceptions of PEN have not changed noticeably since 1986, and we fear that by making it easier for HCFA to effectuate change through its inherent reasonableness authority will only result in a repeat of the situation we faced in 1984-1986.

We share the Committee's frustrations with the sometimes slow pace within HCFA to effectuate needed changes. Section 303 is not unreasonable on its face, as it is logical to attempt to induce HCFA to move more quickly to deal with situations that warrant correction. Based on our past experiences with HCFA on the issues described above, however, we have little confidence that HCFA consistently will use its authority fairly and wisely. Requiring HCFA to act more quickly will not necessarily improve HCFA's decisions on the merits. As is explained below, we believe "inherent reasonableness" authority is not the best way to address payment-related issues.

II. GENERAL OBSERVATIONS ABOUT INHERENT REASONABLENESS

Since 1980, with only a few exceptions, Congress has enacted annual comprehensive changes to the Medicare program as part of the budget reconciliation process. Virtually all of the Medicare Part B-covered items and therapies are subject to payment methodologies mandated by Congress. These methodologies are often fine-tuned by Congress over time. If there is a particular area where the fee schedule or payment methodology needs modification, Congress has not hesitated to do so.

Inherent reasonableness, on the other hand, is an extraordinary remedy, intended primarily to address truly abusive situations. It is less of a process than it is a license for HCFA to disrupt the normal order of policymaking on a particular payment issues. It should be used, if at all, in a focused manner. The legislative history does not suggest that Congress intended for HCFA to use "inherent reasonableness" to substitute its judgement for Congress', and in doing so wipe away years of analysis and work that resulted in the current payment statutes. If HCFA believes that a payment adjustment is in order, then the best course is for HCFA to come to Congress and make its case for a change in reimbursement methodology. The proposed change could be tested in public hearings and subjected to public comment. In the alternative, the next best course is to maintain the current due process protections of notice and comment that exist in the current inherent reasonableness statute, and not require HCFA to meet an artificial deadline for producing a payment rate change.

NATIONAL ALLIANCE FOR INFUSION THERAPY

Thank you for this opportunity to comment on H.R. 3224. If the Committee has any questions about any issue raised in these comments, please contact Alan K. Parver at 202-624-7225.

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